

9/30/96 4:23 pm

Release Tracking Sheet

Bp number: 96-337-01K

Intro type: Release Renewal Permit:
Received: 12/2/96 Clock stop: Clock start: Due:
Institution: Monsanto
Resp person: (b) (6), (b) (7)(C)
Recipient: perched
Status: Sites: 2 Acre: 1.0
Reviewer: VM?
CBI status: CBI
Phenotype: FR/PQ - Fungal resistant/Fruit ripening altered
Comments:
Parsed name: Monsanto Company/BSEK
Address1: 700 Chesterfield Parkway North
Address2:
Address3:
Address4:
City/State: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax:

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[]	[]
2. <input type="checkbox"/> Letter of notification to Applicant	[]	[]
3. <input checked="" type="checkbox"/> File and this tracking sheet to reviewer	[]	[]
4. <input checked="" type="checkbox"/> Letter of preliminary assessment to State	[]	[]
5. <input checked="" type="checkbox"/> Reviewer checks data entries and returns this sheet to permit unit	[]	[]
6. <input type="checkbox"/> State response listed by State/Region/Sites		
CA WR 2 State Response	[]	[]
7. <input checked="" type="checkbox"/> Permit issued or deried	[]	[]
8. <input type="checkbox"/> Enter final data into database	[]	[]

Problem		==CURRENT IN DATABASE==	
Bp number: 16-337-01R	Intro type:	Renewal Permit:	Received:
Clock stop:	Clock start:	Due:	Issue/deny:
Institution:		Resp person:	
Recipient:			
Status:	Sites:	Acre:	Reviewer:
Location:			CBI status:
Comments:			
Category:			
Phenotype:			
SM?:	Gene:	Donor:	
not S			

=====COMMON PREVIOUS ENTRIES AND COUNT FOR GENES, DONORS, AND PHENOTYPES=====

Category:	AP	BR	FR	HT	IR	MG	NR	OO	PQ	VR	
Gene:							Donor:				Phenotype:

12/02/96 1:54 pm

Release Tracking Sheet

FILE COPY

Bp number: 96-337-01r

Intro type: Release Renewal Permit:
Received: Clock stop: Clock start: Due: 12/02/96
Institution: Monsanto
Resp person: (b) (6), (b) (7)(C)
Recipient: Wheat
Status: Pending Sites: 2 Acre: 1.00
Reviewer: VM
CBI status: CBI
Phenotype:
Comments:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 314-537-7085

4/2/97
Due: 12/02/96

Completed
12/18/96
LAW

	Initial	Date
1. [] Assign Bp number and initial data entry	[LU]	[12/3/96]
2. [] Letter of notification to Applicant	[]	[]
3. [] File and this tracking sheet to reviewer	[]	[]
4. [] Letter of preliminary assessment to State	[]	[12/16/96]
5. [] Reviewer checks data entries and returns this sheet to permit unit	[GSM]	[12-10-96]
6. [] State response listed by State/Region/Sites		
CO WR 1	[CH]	[12/26/96]
WA WR 1	[CH]	[1/3/97]
7. [] Permit issued or denied	[]	[]
8. [] Enter final data into database	[]	[]

Entered DB
12/13/96
LAW

cy of appl to
RAS 12/16
for St. Ltr
LAW

Release Gene Data Entry Tracking Sheet

=====CURRENT IN DATABASE=====									
Bp number: 96-337-01r		Intro type: Release		Renewal Permit:			Received:		
Clock stop:		Clock start:		Due: 12/02/96			Issue/deny:		
Institution: Monsanto				Resp person: Edwards, Ramona G.					
Recipient: Wheat									
Status: Pending		Sites: 2		Acre: 1.00		Reviewer: VM		CBI status: CBI	
Location: CO WA									
Comments:									

SM? : ☒ SM

Gene: *ompH*

Donor: *E. coli*

=====COMMON PREVIOUS ENTRIES AND COUNT FOR GENES, DONORS, AND PHENOTYPES=====

Category:	AP	BR	FR	HT	IR	MG	NR	OO	PQ	VR
Gene:							Donor:			Phenotype:

—	—	C B1
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12/02/96 1:54 pm

Release Tracking Sheet

DRAFT

Bp number: 96-337-01r

Intro type: Release Renewal Permit:
Received: 12/2/96 Clock stop: Clock start: Due: 12/02/96
Institution: Monsanto
Resp person: (b) (6), (b) (7)(C)
Recipient: Wheat
Status: Pending Sites: 2 Acre: 1.00
Reviewer: VM
CBI status: CBI
Phenotype:
Comments:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 314-537-7085

	Initial	Date
1. [] Assign Bp number and initial data entry	[lll]	[12/3/96]
2. [] Letter of notification to Applicant	[]	[]
3. [] File and this tracking sheet to reviewer	[]	[]
4. [] Letter of preliminary assessment to State	[]	[]
5. [] Reviewer checks data entries and returns this sheet to permit unit	[]	[]
6. [] State response listed by State/Region/Sites		
CO WR 1 State Response	[]	[]
WA WR 1 State Response	[]	[]
7. [] Permit issued or denied	[]	[]
8. [] Enter final data into database	[]	[]

12/02/96 1:55 pm

Release Gene Data Entry Tracking Sheet

Reviewer of this sheet >>>> DH JW KR SG SK SS VM <<<< Please mark one

Problem >>>>

=====CURRENT IN DATABASE=====

Bp number: 96-337-01r	Intro type: Release	Renewal Permit:	Received:
Clock stop:	Clock start:	Due: 12/02/96	Issue/deny:
Institution: Monsanto		Resp person: Edwards, Ramona G.	
Recipient: Wheat			
Status: Pending	Sites: 2	Acre: 1.00	Reviewer: VM
Location: CO WA			CBI status: CBI
Comments:			

Category:

Phenotype:

SM?:	Gene:	Donor:
SM		

=====COMMON PREVIOUS ENTRIES AND COUNT FOR GENES, DONORS, AND PHENOTYPES=====

Category: AP	BR	FR	HT	IR	MG	NR	OO	PQ	VR
Gene:									

OR120018_BR_011961

Notice

Confidential Business Information

Some information in the attached material may be entitled to treatment as trade secret or proprietary data under Section(b)(4) of the Freedom of Information Act (FOIA) [5 U.S.C. 552(b)(4)].

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure during possession.

Maintain this document under secure conditions.

Return to the Document Control Officer after use.

This application deals with:

96-337-01R

Identification Number:

The attached information is not to be published, reproduced, publicly discussed, included in response to a FOIA request, or otherwise released without the explicit written authorization of the appropriate division director or designee.

**Please disqualify yourself
if there is any potential
Conflict of Interest**

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR 96-202PR
COURTESY PERMIT UNDER 7 CFR 340
(Genetically Engineered Organisms or Products)

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT (b) (6), (b) (7)(C) Monsanto Company/BB1K 700 Chesterfield Parkway North St. Louis, MO 63198		2. PERMIT REQUESTED ("X" one) <input type="checkbox"/> Limited - Interstate Movement <input type="checkbox"/> Limited - Importation <input checked="" type="checkbox"/> Release into the Environment <input type="checkbox"/> Courtesy Permit	3. THIS REQUEST IS ("X" one) <input checked="" type="checkbox"/> New <input type="checkbox"/> Renewal <input type="checkbox"/> Supplemental
4. TELEPHONE NUMBER (b) (6), (b) (7)(C)		5. MEANS OF MOVEMENT <input type="checkbox"/> Mail <input type="checkbox"/> Baggage or Handcarried <input type="checkbox"/> Common Carrier By whom _____	

6. GIVE THE FOLLOWING (if applicable) (if more space is needed, attach additional sheet)

Scientific Name

Common Name

Trade Name

Other Designation

a. Donor Organism: See Attached

b. Recipient Organism:

c. Vector or Vector Agent:

d. Regulated Organism or Product:

e. If product, list names of constituents:

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS NA	8. DATE (or inclusive dates of period) OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE February 27, 1997 - February 26, 1998
9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE See Attached	10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE See Attached
11. ANY BIOLOGICAL MATERIAL (e.g., culture medium, or host material) ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT None	

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

Not Applicable

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than \$10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON (b) (6), (b) (7)(C)		15. PRINTED NAME AND TITLE (b) (6), (b) (7)(C)		16. DATE November 27, 1996
FOR APHIS USE ONLY				
State Notification Sent		State Review Received		Permit Issued <input type="checkbox"/> Yes <input type="checkbox"/> No
Date of Determination	Permit No.	No. of Permit Labels Issued		Supplemental Conditions Enclosed <input type="checkbox"/> Yes <input type="checkbox"/> No
Signature of BBEP Official		Date		Expiration Date

OR120018 BR 011963

APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of transgenic wheat which has been modified to be herbicide tolerant. All of the information required to support this permit is found in this application.

The plasmid vector constructs that will be a part of these field experiments are: PV-TXCT38, PV-TXNM05, and PV-TXNM06.

Item 6. The following is the information required to identify the donor, recipient and regulated organisms and vector agent:

a. For the plasmid vector PV-TXCT38 (PV-TXNM01 + PV-TXHS03 and PV-TXSM04)

Plasmid Vector PV-TXNM01:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	(b) (4)	
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector or Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

Plasmid Vector PV-TXHS03:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	(b) (4)	
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

Plasmid Vector PV-TXSM04:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	(b) (4)	
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

b. For the Plasmid Vector PV-TXNM05:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	(b) (4)	
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

c. For the Plasmid Vector PV-TXNM06:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	(b) (4)	
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

Item 9. The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the (b) (4) The seed was generated from laboratory trials conducted at Monsanto Company.

Item 10. The location of the field experiments:

Weld County, Colorado

(b) (4)

Walla Walla County, Washington

(b) (4)

Item 13a. The transgenic wheat that is the subject of this permit request was developed by scientists at Monsanto.

Item 13b. All of the testing, to date, suggests that the modified plants are identical morphologically, structurally, physiologically, etc., to the non-modified parental variety.

Item 13c. The following is a detailed description of the molecular biology of the system used to produce the regulated article.

Co-Transformation Event (PV-TXNM01 + PV-TXHS03 and PV-TXSM04)

CONSTRUCT DESCRIPTION FOR PV-TXNM01

This construct is a purified insert vector. It contains two genes, including the selectable marker, and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follow. The order of the description for each chimeric gene is the promoter, coding region, and the 3' non-translated end.

MEP 1 (Monocot seed enhanced promoter 1 plus intron) is used to direct expression of foreign genes in the seeds of monocot plants.

CBI

(b) (4)

CME41 - Expression of CME41 (carbohydrate metabolizing enzyme) in plants alters the carbohydrate metabolic pathway.

CBI

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa (b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313:810-812) with the duplicated enhancer region (Kay et al. 1987, Science 236:1299-1302).

CBI

(b) (4)

NPT II - Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXHS03

This construct is a free delivery: pUC-Kan vector containing 1 gene and is delivered to the recipient organism using the particle gun. The order of the descriptions for this gene is promoter, coding region, and 3' non-translated end.

MEP1 - (Monocot seed enhanced promoter 1 plus intron) is used to direct expression of foreign genes in the seeds of monocot plants.

CBI

(b) (4)

CME9 - Expression of CME9 (carbohydrate metabolizing enzyme) in plants alters the carbohydrate metabolic pathway.

CBI

(b) (4)

NOS 3' - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI

CMoVa (b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al. 1987, Science 236:1299-1302).

CBI

(b) (4)

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXNM05

This construct is a purified insert vector. It contains two genes, including the selectable marker, and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follow. The order of the description for each chimeric gene is the promoter, coding region, and 3' non-translated end.

CMoVa (b) (4) - A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI

(b) (4)

NME3 - Expression of NME3 (nitrogen metabolizing enzyme) in plants alters the nitrogen metabolic pathway.

CBI

(b) (4)

NOS 3' - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa (b) (4) - A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI

(b) (4)

NPTII - Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXNM06

This construct is a purified insert vector. It contains 2 genes, including the selectable marker, and is delivered to the recipient organism using the particle gun Mon. The description of the genes in this construct follow. The order of the description for each chimeric gene is the promoter, coding region and 3' non-translated end.

CMoVa (b) (4)

A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

(b) (4)

NME2

Expression of NME2 (nitrogen metabolizing enzyme) in plants alters the nitrogen metabolic pathway.

(b) (4)

NOS 3

A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa (b) (4)

A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

(b) (4)

NPTII

Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3

A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, *Nature* 327: 70-73; 1988a, *Bio/Technology* 6: 559-563; and 1988b, *Proc Natl Acad Sci USA* 85: 4305-4309). The transgenic material in this application was produced using the commercially available particle delivery systems. Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic ($\sim 1 \mu$ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5 μ l) of the coated particles is accelerated at a high velocity allowing the particles to penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring herbicide resistance. The plant cells are grown in the presence of an appropriate antibiotic or herbicide, and only the transformed cells continue to grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in high copy *E. coli* plasmids.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The β -lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the proposed experiment for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the following protocol:

Purpose of the test:

The purpose is to evaluate agronomic performance, yield and yield components of the lines.

Investigators:

Monsanto Principle Investigator

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) MC (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) fax)

Site Investigators

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) CO

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) WA

Site Security:

(b) (4), (b) (6), (b) (7)(C)

Agronomic Practices:

Ground preparation and fertility: ground preparation will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

Disease control: Diseases may be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present may be applied as needed, including seed treatments or topical applications.

Isolation:

The experiment will be surrounded by a 20-foot border of wheat to prevent outcrossing to wheat or other species not a part of this trial.

Monitoring protocols of adequate duration are required to ensure that all volunteers resulting from the field testing of a genetically engineered crop are identified and eliminated.

Plot Design:

The experiment will be a randomized complete block with up to three replicates per treatment. The total area to be planted to the transgenic plants will be up to one acre.

Tentative Schedule:

Planting will be between March 15, 1997 and May 30, 1997 depending on the weather and seed availability. Harvesting will be between July 1, 1997 and August 31, 1997 depending on weather and date of planting.

Harvest Procedures:

The plots will either be harvested by hand or with a small plot combine. If the combine is used, it will be thoroughly cleaned following completion of the plot harvesting and before leaving the plot area.

After harvesting, the test plots will be tilled to destroy the plant material. The plot area will be monitored for one year for surviving plants, which will be destroyed by hand, tillage or herbicide. Wheat or another small grain crop will not be planted in this area for one year.

Item 13f. To avoid accidental mixing and loss, the shipping and maintenance of genetic engineered seeds and plants will include double containment, and devitalization of seeds and other material capable of propagation prior to disposal.

Item 13g. The wheat seed will be shipped to the location specified in item 10. Once received, the seed will be stored in a contained storage facility and used for field release. Any unused seed will be retained for later use or returned to Monsanto, St. Louis.

Item 13h. Once received, the seed will be stored in a locked storage facility and used for field release.

Item 13i. Any unused seed will be retained for later use or returned to Monsanto, St. Louis. For future use, the field will be planted to a crop other than wheat. Any wheat volunteer plants will be removed during the following season.

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

<u>Page</u>	<u>Category of Information</u>	<u>Justification</u>
1	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
2	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
4	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms

3	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
4	Description of Gene/Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene/Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Gene/Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene/Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

CBI DELETED

See reverse side for
additional information

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR
COURTESY PERMIT UNDER 7 CFR 340
(Genetically Engineered Organisms or Products)

96-202PR

INSTRUCTIONS: Complete this form and
enclose the supporting materials listed on the
reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C) 96-337-01r
Monsanto Company/BB1K
700 Chesterfield Parkway North
St. Louis, MO 63198

2. PERMIT REQUESTED ("X" one)

- ☐ Limited - Interstate Movement
☐ Limited - Importation
☒ Release into the Environment
☐ Courtesy Permit

3. THIS REQUEST IS ("X" one)

- ☒ New
☐ Renewal
☐ Supplemental

4. TELEPHONE NUMBER

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- ☐ Mail ☐ Baggage or Handcarried
☐ Common Carrier By whom _____

6. GIVE THE FOLLOWING (if applicable) (if more space is needed, attach additional sheet)

Scientific Name

Common Name

Trade Name

Other Designation

a. Donor Organism: See Attached

b. Recipient Organism:

c. Vector or Vector Agent:

d. Regulated Organism or Product:

e. If product, list names of constituents:

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE
AND NUMBER OF INTRODUCTIONS

NA

8. DATE (or inclusive dates of period) OF IMPORTATION, INTERSTATE MOVEMENT,
OR RELEASE

February 27, 1997 - February 26, 1998

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See Attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF
RELEASE

See Attached

11. ANY BIOLOGICAL MATERIAL (e.g., culture medium, or host material) ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT

None

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

Not Applicable

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than \$10,000 or imprisonment for not more than 5 years or both. (*8 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON

(b) (6), (b) (7)(C)

15. PRINTED NAME AND TITLE

(b) (6), (b) (7)(C)

16. DATE

November 27, 1996

FOR APHIS USE ONLY

State Notification Sent

State Review Received

Permit Issued

☐ Yes ☐ No

Date of Determination

Permit No.

No. of Permit Labels Issued

Supplemental Conditions Enclosed

☐ Yes ☐ No

Signature of BBEP Official

Date

Expiration Date

OR120018_BR_011981

APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of transgenic wheat which has been modified to be herbicide tolerant. All of the information required to support this permit is found in this application.

The plasmid vector constructs that will be a part of these field experiments are: PV-TXCT38, PV-TXNM05, and PV-TXNM06.

Item 6. The following is the information required to identify the donor, recipient and regulated organisms and vector agent:

a. For the plasmid vector PV-TXCT38 (PV-TXNM01 + PV-TXHS03 and PV-TXSM04)

Plasmid Vector PV-TXNM01:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	[[]]
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector or Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

Plasmid Vector PV-TXHS03:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	[[]]
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

Plasmid Vector PV-TXSM04:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	[]
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

b. For the Plasmid Vector PV-TXNM05:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	[[]]
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

c. For the Plasmid Vector PV-TXNM06:

<u>Name</u>	<u>Scientific Name</u>	<u>Common Name</u>
a. Donor Organism	[]
b. Recipient Organism	<i>Triticum aestivum</i>	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	<i>Triticum aestivum</i>	wheat

Item 9. The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The seed was generated from laboratory trials conducted at Monsanto Company.

Item 10. The location of the field experiments:

Weld County, Colorado

(b) (6), (b) (7)(C), (b) (4)

Walla Walla County, Washington

(b) (6), (b) (7)(C), (b) (4)

Item 13a. The transgenic wheat that is the subject of this permit request was developed by scientists at Monsanto.

Item 13b. All of the testing, to date, suggests that the modified plants are identical morphologically, structurally, physiologically, etc., to the non-modified parental variety.

Item 13c. The following is a detailed description of the molecular biology of the system used to produce the regulated article.

CBI.DELETED

Co-Transformation Event (PV-TXNM01 + PV-TXHS03 and PV-TXSM04)

CONSTRUCT DESCRIPTION FOR PV-TXNM01

This construct is a purified insert vector. It contains two genes, including the selectable marker, and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follow. The order of the description for each chimeric gene is the promoter, coding region, and the 3' non-translated end.

MEP 1 (Monocot seed enhanced promoter 1 plus intron) is used to direct expression of foreign genes in the seeds of monocot plants.

[

CBI

]

CME41 - Expression of CME41 (carbohydrate metabolizing enzyme) in plants alters the carbohydrate metabolic pathway.

[

CBI

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa[] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [

]

NPT II - Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXHS03

This construct is a free delivery: pUC-Kan vector containing 1 gene and is delivered to the recipient organism using the particle gun. The order of the descriptions for this gene is promoter, coding region, and 3' non-translated end.

MEP1 - (Monocot seed enhanced promoter 1 plus intron) is used to direct expression of foreign genes in the seeds of monocot plants.

CBI [

]

CME9 - Expression of CME9 (carbohydrate metabolizing enzyme) in plants alters the carbohydrate metabolic pathway.

CBI [

]

NOS 3' - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI CMoVa[] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313:810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [

]

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXNM05

This construct is a purified insert vector. It contains two genes, including the selectable marker, and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follow. The order of the description for each chimeric gene is the promoter, coding region, and 3' non-translated end.

CMoVa/[] - A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313:810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [

]

NME3 - Expression of NME3 (nitrogen metabolizing enzyme) in plants alters the nitrogen metabolic pathway.

CBI [

]

NOS 3' - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa/[] - A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313:810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [

]

NPTII - Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXNM06

This construct is a purified insert vector. It contains 2 genes, including the selectable marker, and is delivered to the recipient organism using the particle gun Mon. The description of the genes in this construct follow. The order of the description for each chimeric gene is the promoter, coding region and 3' non-translated end.

CMoVa/I 1

A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

[

]

NME2

Expression of NME2 (nitrogen metabolizing enzyme) in plants alters the nitrogen metabolic pathway.

[

]

NOS 3

A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa/I 1

A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

[

]

NPTII

Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3

A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, *Nature* 327: 70-73; 1988a, *Bio/Technology* 6: 559-563; and 1988b, *Proc Natl Acad Sci USA* 85: 4305-4309). The transgenic material in this application was produced using the commercially available particle delivery systems. Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5 μ l) of the coated particles is accelerated at a high velocity allowing the particles to penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring herbicide resistance. The plant cells are grown in the presence of an appropriate antibiotic or herbicide, and only the transformed cells continue to grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in high copy *E. coli* plasmids.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The β -lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the proposed experiment for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the following protocol:

Purpose of the test:

The purpose is to evaluate agronomic performance, yield and yield components of the lines.

Investigators:

Monsanto Principle Investigator

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) MC

(b) (6), (b) (7)(C), (b) (4)
(fax)

Site Investigators

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

CO

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) WA

(b) (6), (b) (7)(C), (b) (4)

Site Security:

(b) (6), (b) (7)(C), (b) (4)

Agronomic Practices:

Ground preparation and fertility: ground preparation will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

Disease control: Diseases may be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present may be applied as needed, including seed treatments or topical applications.

Isolation:

The experiment will be surrounded by a 20-foot border of wheat to prevent outcrossing to wheat or other species not a part of this trial.

Monitoring protocols of adequate duration are required to ensure that all volunteers resulting from the field testing of a genetically engineered crop are identified and eliminated.

Plot Design:

The experiment will be a randomized complete block with up to three replicates per treatment. The total area to be planted to the transgenic plants will be up to one acre.

Tentative Schedule:

Planting will be between March 15, 1997 and May 30, 1997 depending on the weather and seed availability. Harvesting will be between July 1, 1997 and August 31, 1997 depending on weather and date of planting.

Harvest Procedures:

The plots will either be harvested by hand or with a small plot combine. If the combine is used, it will be thoroughly cleaned following completion of the plot harvesting and before leaving the plot area.

After harvesting, the test plots will be tilled to destroy the plant material. The plot area will be monitored for one year for surviving plants, which will be destroyed by hand, tillage or herbicide. Wheat or another small grain crop will not be planted in this area for one year.

Item 13f. To avoid accidental mixing and loss, the shipping and maintenance of genetic engineered seeds and plants will include double containment, and devitalization of seeds and other material capable of propagation prior to disposal.

Item 13g. The wheat seed will be shipped to the location specified in item 10. Once received, the seed will be stored in a contained storage facility and used for field release. Any unused seed will be retained for later use or returned to Monsanto, St. Louis.

Item 13h. Once received, the seed will be stored in a locked storage facility and used for field release.

Item 13i. Any unused seed will be retained for later use or returned to Monsanto, St. Louis. For future use, the field will be planted to a crop other than wheat. Any wheat volunteer plants will be removed during the following season.

APHIS APPLICATION NO. 96-337-01r
DATE: 12/16/96

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE
INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

_____ State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the
following comments (use additional sheets if necessary):

_____ State does not concur with APHIS' initial review and
offers the following reasons for nonconcurrence (use additional sheets
if necessary):

Name of State Official: _____

Title: _____

Agency or Department:

Address:

City, State, Zip Code:

Signature: _____

Date: _____

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. VEDPAL MALIK
USDA, APHIS, PPQ, BSS
Biotechnology Evaluation
4700 River Road, Unit 147
Riverdale, MD 20737

OR120018_BR_011994

FILE COPY

APHIS APPLICATION NO. 96-337-01r
DATE: 12/16/96

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE
INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

 X State concurs with APHIS' initial review.

 State concurs with APHIS' initial review and offers the
following comments (use additional sheets if necessary):

 State does not concur with APHIS' initial review and
offers the following reasons for nonconcurrence (use additional sheets
if necessary):

Name of State Official: Leslie A. Zermuehlen

Title: Chief, Plant and Insect Section

Agency or Department: Colorado Department of Agriculture
Division of Plant Industry

Address: 700 Kipling Street, Suite 4000

City, State, Zip Code: Lakewood, CO 80215-5894

Signature: (b) (6), (b) (7)(C)

Date: December 20, 1996

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. VEDPAL MALIK
USDA, APHIS, PPQ, BSS
Biotechnology Evaluation
4700 River Road, Unit 147
Riverdale, MD 20737

RECEIVED
12/26/96

DELVD
TO RVR=12/26/96

OR120018_BR_011995

FILE COPY

APHIS APPLICATION NO. 96-337-01r
DATE: 12/16/96

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE
INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

X State concurs with APHIS' initial review.

 State concurs with APHIS' initial review and offers the
following comments (use additional sheets if necessary):

 State does not concur with APHIS' initial review and
offers the following reasons for nonconcurrence (use additional sheets
if necessary):

Name of State Official: Thomas L. Wessels

Title: Plant Pathologist

Agency or Department:

WA. ST. Dept. of Agriculture - Laboratory Services

Address: 24106 N. Bunn Rd.

City, State, Zip Code: Prosser, WA. 99350

Signature: (b) (6), (b) (7)(C)

Date: 12/30/96

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. VEDPAL MALIK
USDA, APHIS, PPQ, BSS
Biotechnology Evaluation
4700 River Road, Unit 147
Riverdale, MD 20737

OR120018_BR_011996

RECEIVED
1/3/97

B69

96-33701

*Assessment Worksheet (AW) for Release Permits - Biotechnology Permits
Version 1.0 - March 3, 1995*

BP's Permitting activities are categorically exempt from the NEPA requirements if the field test permit is for a plant species that meets the following criteria:

- (1) The plant species has previously been the subject of an EA prior to release under APHIS permit, and
- (2) The "trait" engineered into the plant is not new and its introduction in the plant does not "raise any new issues" with respect to environmental impacts

If the reviewer can answer "yes" to point #1, then the rest of the AW should be completed in order to be able to answer point #2. If, after completing the AW, the reviewer can answer "yes" to point #2, there is no need for an EA before the permit is issued. The reviewer should place the AW in the file for the permit.

If, after completing the AW, the reviewer can not answer "yes" to both points #1 and #2 above, then it will be necessary to prepare an EA before a permit is issued.

Complete the required for database information, including

1. Indicate all gene(s) and source organisms: [GENE LIST]

2. Indicate recipient species:

Triticum aestivum

THEN,

3. For insect resistant (IR) phenotype, check site(s) of tests for there threatened and endangered species:

- ☒ NO, threatened and endangered species are not likely to be affected
☐ YES, threatened and endangered species likely to be affected

4. Containment protocol:

☒ proposed protocol is adequate (at least as good as that used for APHIS Permit _____)

☐ proposed protocol is inadequate and modified in consultation with applicant in the following way(s):

5. Devitalization and monitoring for volunteers:

☒ proposed protocol is adequate (at least as good as that used for APHIS Permit _____)

☐ proposed protocol is inadequate and modified in consultation with applicant in the following way(s):

6. Physical (separated from surrounding plants to prevent mixing):

☒ proposed protocol is adequate (at least as good as that used for APHIS Permit _____)

☐ proposed protocol is inadequate and modified in consultation with applicant in the following way(s):

NOTE: ITEMS 7 & 8 ARE ALSO INTENDED TO HELP THE BIOTECHNOLOGIST FACILITATE ANY OTHER REGULATORY REQUIREMENTS THAT THE APPLICANT MAY FACE (FOR EXAMPLE, REQUIREMENTS OF APHIS-PPQ, EPA, OR THE STATES)

7. Will there be challenge inoculations as part of the test?

☒ NO

☐ YES (Challenge viral inocula may "raise new issues", such as potential for recombination, and thereby trigger the need for a full EA.)

8. Will the applicant need other permits (such as interstate movement of plant pathogens)

☒ NO

☐ YES

9. Conclusion regarding impact on the environment (equivalent to FONSI).

For example: If any of the following criteria are true for a release permit application, we will prepare an EA:

- 1. New crop species (never field tested before under APHIS Permit)*
- 2. Regulated article is a microorganism*
- 3. The trait(s) introduced would not qualify under the NOTIFICATION eligibility criteria*

** an exception would be virus genes (such as replicase, movement proteins, etc.) that would not qualify under notification, but we have previously considered these genes in the same crop (in consideration of potential recombination among viruses that can infect the same host species). This would be an example where the trait and plant have been evaluated before, but the consideration of new recombination opportunities would "raise new issues" (see the first two criteria on page one).*

V. J. Smalick

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

November 27, 1996

Ms. E. Dianne Hatmaker
Biotechnology, Biologics, and Environmental Protection
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737-1237

Subject: Request for Field Release Permit
Monsanto # 96-202PR

Dear Ms. Hatmaker:

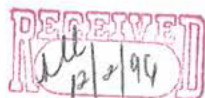
Please find attached a permit request for the Release of a Regulated Organism, Wheat. This release will be conducted in the states of Colorado and Washington. In support of this request, please find a completed APHIS Form 2000 and supporting information for the vectors.

This release contains confidential business information (CBI) and is so marked. This confidential information was developed by Monsanto at its own expense, has not been released to anyone not under a secrecy agreement to Monsanto and has not been published. We request that this information not be released as it has value to our competitors (domestic and foreign) in that they would be able to copy this work and unfairly compete with us causing financial loss and other harm to Monsanto.

We appreciate your attention to this matter. Should you have any questions, please feel free to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)



OR120018_BR_012000

FILE

16 DEC 1996

Mr. Daniel J. Williams
Plant Pathology Program Manager
Plant Services Branch
Washington State Department of Agriculture
406 General Administration Building AX-41
Olympia, WA 98504

Re: APHIS Preliminary Review of an Application by the Monsanto
Agricultural Company to Field Test Genetically Engineered Wheat
Plants. Accession Number 96-337-01r.

Dear Mr. Williams:

This letter contains our preliminary review of an application submitted by Monsanto Agricultural Company for a permit that would allow the field testing of genetically engineered wheat (*Triticum aestivum*) for herbicide tolerance. The plants have been genetically modified for increased carbohydrate and nitrogen metabolism. In addition, the plants have been transformed with the *nptII* (neomycin phosphotransferase) gene which serves as a selectable marker. The field test will start on or about April 1, 1997 in Weld County Colorado and Walla Walla County Washington.

The Monsanto Agricultural Company application was submitted pursuant to the regulations found in 7 CFR Part 340, which regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products that are regulated articles. Under the regulations, an organism is considered a regulated article if it is genetically engineered (as defined in §340.1) from a donor organism, recipient organism, or vector or vector agent which is listed in §340.2 of the regulations, and the listed organism is a plant pest (as defined in §340.1). The regulations require that a person obtain a permit from the Animal and Plant Health Inspection Service (APHIS) prior to introducing a regulated article.

Pursuant to the procedures set forth in §340.3 of the regulations, we have prepared our preliminary findings in this letter for your review. This serves to give notice to the State and to provide the opportunity for the State to expressly indicate concurrence or nonconcurrence with our preliminary assessment. Please review the enclosed application documents and return acknowledgement, associated comments, and concurrence or reasons for nonconcurrence (if applicable) to APHIS within 30 days of receipt of this letter. Please use the enclosed form, and use additional sheets if needed for your response. It is very important that our office receive comments and opinions from State regulatory officials regarding the issuance of permits for the release of genetically engineered organisms into the environment. On

OR120018_BR_012001

the basis of our preliminary review of this application, we conclude that controlled field testing of the genetically engineered wheat plants described in this application will not present any risk of plant pest introduction or dissemination for the reasons cited below.

1. Environmental Impacts Related to the Recipient. The recipient organisms are wheat plants. Wheat is normally self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions. Thus, there is a lack of gene movement. To prevent any mechanical mixing, a minimum of 20 feet distance will be maintained between the transgenic and nontransgenic wheat plants.

2. Environmental Impacts Related to the Donor. The wheat plants for this field test have been altered via genetic engineering techniques to express genes for increased nitrogen and carbohydrate metabolism. The nature of the gene has been claimed as confidential business information by the applicant. Other gene transferred to wheat is a selectable marker, the neomycin phosphotransferase II (*nptII*), that enables plants to grow on medium containing kanamycin. Even though DNA sequences isolated from various plant pests (caulimovirus promoter plus intron, *Agrobacterium tumefaciens*) have been used to regulate the expression of introduced genes, they do not confer any plant pest risk on the recipient wheat plants by themselves or in conjunction with associated genes. None of the introduced genes or regulatory sequences confer any plant pest risk on the recipient wheat plants by themselves or in conjunction with associated genes. No changes in the gross biological properties of wheat are expected; any deleterious effects on wheat would be confined to the wheat plants in this field trial.

Noncoding DNA regulatory sequences (promoters and terminators) were attached to the introduced genes to facilitate expression in plants. These regulatory sequences were derived from known plant pests, specifically cauliflower mosaic virus and Ti plasmid of *Agrobacterium tumefaciens*. None of the DNA regulatory sequences can cause plant disease by themselves or in conjunction with the genes that were introduced into the transgenic plants.

3. Environmental Impacts Related to the Vector and Vector Agent. The wheat plants in this experiment were transformed using the method of particle acceleration, also referred to as the biolistic or particle gun method of transformation. Plant tissues are bombarded with heavy particles, typically tungsten or gold, that are coated with DNA, with the result that particles are able to penetrate the barriers of the cell wall and the cell membrane and deliver the DNA to the interior of the cell. Research experience with transgenic plants produced by the particle acceleration method indicates that the engineered genes are typically integrated into the nuclear genome and segregate in a Mendelian fashion in subsequent generations. No plant pest risk associated with this method of transformation can be identified.

4. Quarantine of Organism and Final Disposition. Plot design will be completely randomized block. After sampling, the test plot will be tilled to destroy the plant material. After termination of the experiment, the test site will be monitored for one month for surviving plants, which will be destroyed by hand, tillage or herbicide treatment. The containment measures described in the application should be sufficient to minimize any unplanned releases of the transgenic plant material.

Staff Contact

If you have any questions about this application or our preliminary findings, please contact Dr. Ved Malik, Biotechnologist, at Area Code (301) 734-6774 or facsimile number (301) 734-8910. Please refer to permit application number 96-337-01r in your correspondence regarding this application. APHIS hopes to maintain its excellent working relationship with your State and encourages your participation and comments prior to our final decision.

Sincerely,

(b) (6), (b) (7)(C)

Ved Malik, Ph.D.
Biotechnologist
Biotechnology Evaluation

2 Enclosures
Permit Application 96-337-01r
State Response Form

cc:
R. Stoaks, PPQ, Moorestown, NJ
File 96-337-01r

IDENTICAL LETTERS SENT TO:

Mr. Leslie A. Zermuehlen
Colorado Department of Agriculture
700 Kipling Street, Suite 400
Lakewood, CO 80215-5894

APHIS:BBEP:BP:VMALIK:RAS:734-6774:12/12/96:I:\STATE:96033701R.STL

FILE

JAN 13 1997

(b) (6), (b) (7)(C)

Monsanto Company/BB1K
700 Chesterfield Parkway North
St. Louis, MO 63198

Subject: Biotechnology Permit Number 96-337-01r to Conduct a Planned Release of Genetically Engineered *Wheat* Plants

The above permit has been approved after a Finding of No Significant Impact (FONSI) and a finding that the genetically engineered organisms do not present a risk of plant pest introduction or dissemination. You must adhere to the standard and supplemental conditions enclosed.

This permit should not be taken as any type of efficacy determination of the genetically engineered organisms.

Sincerely,

/s/ Arnold Foudin

Arnold S. Foudin, Ph.D.
Deputy Director
Biotechnology Permits

Enclosure:
Permit 96-337-01r
Supplemental Permit Conditions
Standard Permit Conditions
Map - Regional Biotechnologists

cc:
L. Zermuehlen, CO Dept. Of Agriculture, Lakewood, CO
D. Williams, WA Dept. Of Agriculture, Olympia, WA
R. Stoaks, PPQ, Sacramento, CA
File 96-337-01r

APHIS:PPQ:BSS:BE:VMALIK:RAS:734-7612:1/13/97:I:ISSUANCES\9633701R.IS

OR120018_BR_012004

10/02/97 1:27 pm

Notification Tracking Sheet

=====

Bp number: 97-275-03n

=====

App number: 97-281XR
Received: 10/02/97
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 11/01/97
Phenotype: HT - Glyphosate tolerant
Comments:

Begin movement:
End movement:
Begin release: 11/01/97
End release: 11/01/98
Acre: 3.00
CBI status: CBI

Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Fax: 314-537-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[aye]	[10/2/97]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[DSH]*	[10/2/97]*
3. <input checked="" type="checkbox"/> Letter of notification to State FEDEX	[bgs]	[10/2/97]*
4. <input type="checkbox"/> State response		

	Release	O/d	Loc	Site	Reg		
	*		*AZ	*	1*WR	*	
5. <input checked="" type="checkbox"/> Enter genes into database							[aye] [10/2/97]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw							[bgs] [10/8/97]*
7. <input checked="" type="checkbox"/> Enter final data into database							[bgs] [10/10/97]

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

October 1, 1997

Ms. E. Dianne Hatmaker
Animal and Plant Health Inspection Service
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, Maryland 20737-1237

1. Reference Number: 97-275-03n

2. Applicant Reference Number: 97-281XR

3. Applicant/Responsible party:

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

(b) (6), (b) (7)(C)

Tel: (b) (6), (b) (7)(C)

Fax: 314/737-7085

4. Duration of Introduction:

Release: November 1, 1997 - November, 1998

5. Recipient: Wheat, *Triticum aestivum*, cultivar Bobwhite

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October 1, 1997
Page 2

6. **Regulated Article:**

designation of transformed lines: T104, T112, T122, T124
category: HT
phenotype: glyphosate tolerant
construct: PV-TXCT01

CBI CMoVa/I2 -

(b) (4)
(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983 Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI CMoVa/I2 -

(b) (4)
(b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI

(b) (4)
(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Page 3

Construct Description for PV-TXCT01 (Cont'd)

selectable marker

CBI **CMoVa/I2** - (b) (4)
cauliflower mosaic virus (CaMV) promoter (Odell et al. 1985, Nature 313-810-812). CMoVa/I2 contains a 0.8 Kb fragment containing the first intron from the maize heat shock protein 70 gene (Shah et al., 1985, Cell. and Mol. Biol of Stress., Alan R. Liss, Inc. pp. 181-200).]

CBI **TMG1** - The expression of this gene is used as a scorable marker for plant transformation.

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Page 4

designation of transformed lines: T228

category: HT

phenotype: glyphosate tolerant

construct: PV-TXCT23

CBI TSP3/I2 - The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI

(b) (4)

AS1 - Expression of this sequence alters the expression of marker genes.

CBI

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI

CMoVa/I2 -

(b) (4)

(b) (4)

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

CBI

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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October 1, 1997
Page 5

Construct Description for PV-TXCT23 (Cont'd)

selectable marker

CBI **TSP3/I2** The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI

(b) (4)

CBI **TMG1** The expression of this gene is used as a marker for plant transformation.

CBI

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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October 1, 1997

Page 6

designation of transformed lines: 1121, 1154

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT02

CMP1/I2 -The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Page 7

Construct Description for PV-TXGT02 (Cont'd)

selectable marker

CMP1/12 - The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI

(b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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 Page 8

designation of transformed lines: 24115, 24117, 24756, 24776, 26248, 28813, 29263, 29264, 29265, 29266, 29271

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT04

CBI CMoVa/I2 - I

(b) (4)

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMP 3/I5 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Notification 97-281XR

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designation of transformed lines: 23021, 23134, 25372, 25397, 25463, 28774, 28777, 28778, 28782, 28783, 28784, 28215

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT05

CMoVa/I5 - A 35Scaulimovirus promoter region plus intron.

CBI

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMP 3/I5 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 26281, 26300, 26907, 27249, 28282, 28286, 29219, 29220

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT06

CMoVa/I5+header2 - A caulimovirus promoter plus intron.

CBI

(b) (4)

CBI CTP2-HMEsyn -[CTP2-HMEsyn (herbicide metabolizing enzyme) is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442) and a synthetic version of the 0.44 Kb *E. coli* phnO gene (Chen et al. 1990, J. Biol Chem 265: 4461-4471) encoding an aminomethylphosphonate acetyltransferase (Barry et al., unpublished).]

M1 3' functions to direct polyadenylation of the mRNA.

CBI

(b) (4)

CMoVa/I5+header1 - A caulimovirus promoter plus intron.

CBI

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

M1 3' functions to direct polyadenylation of the mRNA.

CBI

(b) (4)

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Construct Description for PV-TXGT06 (Cont'd)

CBI CMoVa/I2 -

(b) (4)

(b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Notification 97-281XAB

October 1, 1997

Page 12

designation of transformed lines: 25462, 27841, 28185, 28189, 28190, 28192, 28200, 28204, 28289, 28291, 28294, 28298, 28864

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT07

CMoVa/I5 - A 35Scaulimovirus promoter region plus intron.

CBI

(b) (4)

CBI

CTP2-HMEsyn

(b) (4)

(b) (4)

M1 3' functions to direct polyadenylation of the mRNA.

CBI

(b) (4)

CMoVa/I5+Header2 - A caulimovirus promoter plus intron.

CBI

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

M1 3' functions to direct polyadenylation of the mRNA.

CBI

(b) (4)

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Construct Description for PV-TXGT07 (Cont'd)

CBI CMoVa/I2 -

(b) (4)

(b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI

(b) (4)

NOS - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 29276, 29277, 29279

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT08

CMoVa/I5+leader2 - A caulimovirus promoter plus intron.

CBI

(b) (4)

CBI

CTP2-HME_{syn}

(b) (4)

(b) (4)

CBI

M1 3' functions to direct polyadenylation of the mRNA

(b) (4)

CBI

CMoVd/I5+leader1 - A caulimovirus promoter plus intron.

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI

M1 3' functions to direct polyadenylation of the mRNA.

(b) (4)

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Construct Description for PV-TXGT08 (Cont'd)

CBI CMoVa/I2 -

(b) (4)

(b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 28577, 28579, 28585, 28586, 28597, 28598, 28807

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT09

CMP 3/I5 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI

CMoVa/I2 -

(b) (4)

(b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI

(b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Construct Description for PV-TXGT09 (Cont'd)

CMoVa/I5 - A 35Scaulimovirus promoter region plus intron.

CBI

(b) (4)

CTP2-PMESyn - Expression of CTP2-PMESyn (phosphonate metabolizing enzyme) in plants results in the metabolism of phosphonate herbicides to a less herbicidal form)..

CBI

(b) (4)

M1 3' - functions to direct polyadenylation of the mRNA.

CBI

(b) (4)

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7. **Mode of Transformation:** particle gun

8. **Introduction:**

Release:

NUMBER OF STATES/TERRITORIES AND SITES: AZ (1)

(b) (4), (b) (6), (b) (7)(C) Yuma County, AZ, (b) (4), (b) (6), (b) (7)(C) up to 3 acres.

9. **Certification:** I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

October 1, 1997

(b) (6), (b) (7)(C)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of genetically modified crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

<u>Page</u>	<u>Category of Information</u>	<u>Justification</u>
2	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.

5	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
15	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
16	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.

17	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
18	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
19	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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October 1, 1997

Ms. E. Dianne Hatmaker
Animal and Plant Health Inspection Service
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, Maryland 20737-1237

1. Reference Number: 97-275-03n

2. Applicant Reference Number: 97-281XR

3. Applicant/Responsible party:

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

(b) (4), (b) (6), (b) (7)(C)

Tel: (b) (4), (b) (6), (b) (7)(C)

Fax: 314/737-7085

4. Duration of Introduction:

Release: November 1, 1997 - November 1, 1998

5. Recipient: Wheat, *Triticum aestivum*,, cultivar Bobwhite

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6. **Regulated Article:**

designation of transformed lines: T104, T112, T122, T124

category: HT

phenotype: glyphosate tolerant

construct: PV-TXCT01

CBI CMoVa/I2 - [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983 Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa/I2 - A caulimovirus promoter plus intron.

CBI [

]

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Construct Description for PV-TXCT01 (Cont'd)

selectable marker

CBI [**CMoVa/I2** - A caulimovirus promoter plus intron.
]
]

CBI [**TMG1** - The expression of this gene is used as a scorable marker for plant transformation.
]
]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: T228

category: HT

phenotype: glyphosate tolerant

construct: PV-TXCT23

CBI TSP3/I2 - The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [

]

AS1 - Expression of this sequence alters the expression of marker genes.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa/[I2] - A caulimovirus promoter plus intron.

CBI [

]

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Construct Description for PV-TXCT23 (Cont'd)

selectable marker

CBI **TSP3/I2** The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [

]

TMG1 The expression of this gene is used as a marker for plant transformation.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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designation of transformed lines: 1121, 1154

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT02

CMP1/12 -The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Construct Description for PV-TXGT02 (Cont'd)

selectable marker

CMP1/I2 - The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 24115, 24117, 24756, 24776, 26248, 28813, 29263, 29264, 29265, 29266, 29271

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT04

CMoVa/I2 - A caulimovirus promoter plus intron.

CBI [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

selectable marker

CMP 3/I5 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 23021, 23134, 25372, 25397, 25463, 28774, 28777, 28778, 28782, 28783, 28784, 28215

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT05

CMoVa/I5 - A 35S caulimovirus promoter region plus intron.

CBI [

]

CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMP 3/I5 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 26281, 26300, 26907, 27249, 28282, 28286, 29219, 29220

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT06

CMoVa/I5+leader2 - A caulimovirus promoter plus intron.

CBI [

]

CBI CTP2-HMEsyn -[

]

M1 3' functions to direct polyadenylation of the mRNA.

CBI [

]

CMoVa/I5+leader1 - A caulimovirus promoter plus intron.

CBI [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

M1 3' functions to direct polyadenylation of the mRNA.

CBI [

]

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Construct Description for PV-TXGT06 (Cont'd)

CBI **CMoVa/I2** A caulimovirus promoter plus intron.
[

]

CBI **CTP1-GMEsyn** Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme)
confers glyphosate tolerance in plants.
[

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 25462, 27841, 28185, 28189, 28190, 28192, 28200, 28204, 28289, 28291, 28294, 28298, 28864

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT07

CMoVa/I5 - A caulimovirus promoter plus intron.

CBI [

]

CBI CTP2-HMEsyn -[

]

M1 3' functions to direct polyadenylation of the mRNA.

CBI [

]

CMoVa/I5+Header2 - A caulimovirus promoter plus intron.

CBI [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

M1 3' functions to direct polyadenylation of the mRNA.

CBI [

]

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Construct Description for PV-TXGT07 (Cont'd)

CBI [CMoVa/I2 A caulimovirus promoter plus intron.
]

CBI [CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme)
confers glyphosate tolerance in plants.
]

]

NOS - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene of
Agrobacterium tumefaciens T-DNA (Fraley et al. 1983, Proc Natl Acad Sci USA 80:
4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions
to direct polyadenylation of the mRNA.

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designation of transformed lines: 29276, 29277, 29279category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT08

CBI [CMoVa/I5+leader2 - A caulimovirus promoter plus intron.

]

CBI CTP2-HMEsyn -[

]

CBI [M1 3' functions to direct polyadenylation of the mRNA.

]

CBI [CMoVd/I5+leader1 - A caulimovirus promoter plus intron.

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI [M1 3' functions to direct polyadenylation of the mRNA.

]

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Construct Description for PV-TXGT08 (Cont'd)

selectable marker

CBI [**CMoVa/I2** A caulimovirus promoter plus intron.

]

CBI [**CTP1-GMEsyn** Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 28577, 28579, 28585, 28586, 28597, 28598, 28807

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT09

CMP 3/I5 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa/I2 - A caulimovirus promoter plus intron.

CBI [

]

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Construct Description for PV-TXGT09 (Cont'd)

selectable marker

CBI [CMoVa/I5 - A caulimovirus promoter plus intron.
]

CBI [CTP2-PMESyn - Expression of CTP2-PMESyn (phosphonate metabolizing enzyme) in
plants results in the metabolism of phosphonate herbicides to a less herbicidal form).
]

CBI [M1 3' - functions to direct polyadenylation of the mRNA.
]

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

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7. **Mode of Transformation:** particle gun

8. **Introduction:**

Release:

NUMBER OF STATES/TERRITORIES AND SITES: AZ (1)

(b) (4), (b) (6), (b) (7)(C) Yuma County, AZ (b) (4), (b) (6), (b) (7)(C) up to 3 acres.

9. **Certification:** I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

October 1, 1997

(b) (6), (b) (7)(C)

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

October 1, 1997

Ms. E. Dianne Hatmaker
Animal and Plant Health Inspection Service
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, Maryland 20737-1237

1. Reference Number: 97-275-03n

2. Applicant Reference Number: 97-281XR

3. Applicant/Responsible party:

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

(b) (6), (b) (7)(C)
Tel: (b) (6), (b) (7)(C)
Fax: 314/737-7085

4. Duration of Introduction:

Release: November 1, 1997 - November 1, 1998

5. Recipient: Wheat, *Triticum aestivum*, cultivar Bobwhite

CBI DELETED

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6. Regulated Article:

designation of transformed lines: T104, T112, T122, T124

category: HT

phenotype: glyphosate tolerant

construct: PV-TXCT01

CBI CMoVa/I2 - [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983 Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI CMoVa/I2 - A caulimovirus promoter plus intron.
[

]

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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Construct Description for PV-TXCT01 (Cont'd)selectable marker

CBI [CMoVa/I2 - A caulimovirus promoter plus intron.

]

CBI [TMG1 - The expression of this gene is used as a scorable marker for plant transformation.

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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designation of transformed lines: T228category: HTphenotype: glyphosate tolerantconstruct: PV-TXCT23

CBI TSP3/12 - The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [

]

AS1 - Expression of this sequence alters the expression of marker genes.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa/[I2] - A caulimovirus promoter plus intron.

CBI [

]

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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Construct Description for PV-TXCT23 (Cont'd)selectable marker

CBI TSP3/I2 The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [

]

CBI TMG1 The expression of this gene is used as a marker for plant transformation.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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designation of transformed lines: 1121, 1154
category: HT
phenotype: glyphosate tolerant
construct: PV-TXGT02

CMP1/12 -The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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Construct Description for PV-TXGT02 (Cont'd)

selectable marker

CMP1/12 - The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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designation of transformed lines: 24115, 24117, 24756, 24776, 26248, 28813, 29263, 29264, 29265, 29266, 29271

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT04

CBI [CMoVa/I2 - A caulimovirus promoter plus intron.

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

selectable marker

CBI [CMP 3/I5 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

]

CBI [CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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designation of transformed lines: 23021, 23134, 25372, 25397, 25463, 28774, 28777, 28778, 28782, 28783, 28784, 28215

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT05

CBI [CMoVa/IS - A 35S caulimovirus promoter region plus intron.

]

CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI [CMP 3/IS - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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designation of transformed lines: 26281, 26300, 26907, 27249, 28282, 28286, 29219, 29220

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT06

CBI CMoVa/I5+leader2 - A caulimovirus promoter plus intron.
[

]

CBI CTP2-HMEsyn -[

]

CBI M1 3' functions to direct polyadenylation of the mRNA.
[

]

CBI CMoVa/I5+Header1 - A caulimovirus promoter plus intron.
[

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI M1 3' functions to direct polyadenylation of the mRNA.
[

]

CBI DELETED

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Construct Description for PV-TXGT06 (Cont'd)

CBI **CMoVa/I2** A caulimovirus promoter plus intron.
[

]

CBI **CTP1-GMEsyn** Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme)
confers glyphosate tolerance in plants.
[

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA. 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 25462, 27841, 28185, 28189, 28190, 28192, 28200, 28204, 28289, 28291, 28294, 28298, 28864

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT07

CBI [CMoVa/I5 - A caulimovirus promoter plus intron.

CBI CTP2-HMEsyn -[

CBI [M1 3' functions to direct polyadenylation of the mRNA.

CBI [CMoVa/I5+leader2 - A caulimovirus promoter plus intron.

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI [M1 3' functions to direct polyadenylation of the mRNA.

CBI DELETED

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Construct Description for PV-TXGT07 (Cont'd)

CBI CMeVa/I2 A caulimovirus promoter plus intron.
[

]

CBI CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme)
confers glyphosate tolerance in plants.
[

]

NOS - A 3' non-translated region (0.3 Kb) of the nopaline synthase gene of
Agrobacterium tumefaciens T-DNA (Fraley et al. 1983, Proc Natl Acad Sci USA 80:
4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions
to direct polyadenylation of the mRNA.

CBI DELETED

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designation of transformed lines: 29276, 29277, 29279category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT08

CBI [CMoVa/I5+header2 - A caulimovirus promoter plus intron.

CBI [CTP2-HMEsyn -[

CBI [M1 3' functions to direct polyadenylation of the mRNA.

CBI [CMoVd/I5+header1 - A caulimovirus promoter plus intron.

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI [M1 3' functions to direct polyadenylation of the mRNA.

CBI DELETED

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Construct Description for PV-TXGT08 (Cont'd)selectable marker

CBI [CMoVa/I2 A caulimovirus promoter plus intron.

]

CBI [CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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designation of transformed lines: 28577, 28579, 28585, 28586, 28597, 28598, 28807
category: HT
phenotype: glyphosate tolerant
construct: PV-TXGT09

CMP 3/15 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa/I2 - A caulimovirus promoter plus intron.

CBI [

]

CTP1-GMEsyn Expression of CTP1-GMEsyn (glyphosate metabolizing enzyme) confers glyphosate tolerance in plants.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

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Construct Description for PV-TXGT09 (Cont'd)

selectable marker

CBI [CMoVa/IS - A caulimovirus promoter plus intron.
]

CBI [CTP2-PMEsyn - Expression of CTP2-PMEsyn (phosphonate metabolizing enzyme) in
plants results in the metabolism of phosphonate herbicides to a less herbicidal form).
]

CBI [M1 3' - functions to direct polyadenylation of the mRNA.
]

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 894-1000

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7. Mode of Transformation: particle gun

8. Introduction:

Release:

NUMBER OF STATES/TERRITORIES AND SITES: AZ (1)

(b) (4), (b) (6), (b) (7)(C)

Yuma County, AZ

(b) (4), (b) (6), (b) (7)(C)

up to 3 acres.

9. Certification: I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

October 1, 1997

file copy

Mr. Glen Thaxton, Asst. Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

October 2, 1997

Dear Mr. Thaxton:

Enclosed is notification 97-275-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	97-275-03n	Applicant #:	97-281XR
Received:	October 2, 1997	Effective:	November 1, 1997
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012066



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Glen Thaxton, Asst. Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

October 2, 1997

Dear Mr. Thaxton:

Enclosed is notification 97-275-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	97-275-03n	Applicant #:	97-281XR
Received:	October 2, 1997	Effective:	November 1, 1997
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Steaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Ken Boyd

Signature: (b) (6), (b) (7)(C)

Date: 10/3/97

State: AZ



APHIS • Protecting America's Agriculture

OR120018_BR_012067

An Equal Opportunity Employer

RECEIVED
10/3/97

October 8, 1997

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request number (97-281XR) 97-275-03N, requesting permission to release into the environment the regulated article wheat, under 7 CFR 340.3 (c) is acknowledged. The notification will become effective and **may be executed on or after October 8, 1997, per State Regulatory Official.**

This acknowledgment does not authorize the use of "challenge organisms" for field tests.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official, and the Regional Operations Officer.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Biotechnology and Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

G. Thaxton, Arizona Dept. of Agric., Phoenix, AZ
R. Stoaks, PPQ, WR, Sacramento, CA
File number 97-275-03N

OR120018_BR_012068



October 8, 1997

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request number (97-2013A) 97-275-03N, requesting permission to release into the environment the regulated article wheat, under 7 CFR 340.3 (c) is acknowledged. The notification will become effective and may be executed on or after October 8, 1997, per State Regulatory Official.

This acknowledgment does not authorize the use of "Challenge organisms" for field tests.

You must comply with the performance standards as stated in 7 CFR 340.3 (e). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official, and the Regional Operations Officer.

Sincerely,

(b) (6), (b) (7)(C)

R. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Biotechnology and Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

G. Thaxton, Arizona Dept. of Agric., Phoenix, AZ
R. Steaks, EFQ, WA, Sacramento, CA



APHIS - Promoting American Agriculture

An Equal Opportunity Employer

TRANSMISSION REPORT

THIS DOCUMENT WAS CONFIRMED
(REDUCED SAMPLE ABOVE - SEE DETAILS BELOW)

**** COUNT ****

TOTAL PAGES SCANNED : 1

TOTAL PAGES CONFIRMED : 1

*** SEND ***

No.	REMOTE STATION	START TIME	DURATION	#PAGES	MODE	RESULTS
1	MONSANTO	10- 8-97 4:05PM	0'37"	1/ 1	EC	COMPLETED 9600

TOTAL 0:00'37" 1

NOTE:

No. : OPERATION NUMBER 48 : 4800BPS SELECTED EC : ERROR CORRECT G2 : G2 COMMUNICATION
PD : POLLED BY REMOTE SF : STORE & FORWARD RI : RELAY INITIATE RS : RELAY STATION
MB : SEND TO MAILBOX PG : POLLING A REMOTE MP : MULTI-POLLING RM : RECEIVE TO MEMORY

OR120018_BR_012069

1997 WHEAT FIELD RELEASE
USDA 97-275-03N/MONS # 97-281XR
FINAL REPORT

(b) (6), (b) (7)(C)

Monsanto Company

Location

Milton Johnson Farm

County

Yuma

State

AZ

Yuma County, AZ

Planting Date: October 23, 1997

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

ajd

Monsanto Company

700 Chesterfield Parkway North, St. Louis, Missouri 63198,

Mail Code BB1K

FAX

Date: 12/08/1999

Number of pages including cover sheet: _____

To:

Ms. Susan Koehler

USDA - APHIS

Phone:

Fax phone:

CC:

From:

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis, MO 63198

Phone:

(b) (6), (b) (7)(C)

Fax phone:

(636) 737-7085

REMARKS:



Urgent



For your review



Reply ASAP



Please comment

Dear Ms. Koehler,

Per your request, I am attaching the status of Monsanto wheat trials and seed disposition. At this time, we are continuing to gather information on the final disposition of some of the material.

I will be in contact with you tomorrow regarding this matter.

Regards,

(b) (6), (b) (7)(C)

Field Compliance Specialist

OR120018_BR_012071

WHEAT TRIALS

1997

USDA #	Monsanto #	Status
97-275-03n	97-281XR	Final report submitted 10/20/99 1500lbs seed yield all destroyed in Yuma, AZ
97-289-05n	97-312XRAB	Final report submitted 10/20/99 150lbs seed all destroyed in Yuma, AZ
97-289-06n	97-313XRAB	Final report submitted 10/20/99 1500lbs seed destroyed in Yuma, AZ
97-289-07n	97-314XRAB	Final report submitted 10/20/99 500lbs seed destroyed in Yuma, AZ
97-289-08n	97-315XRAB	Final report submitted 10/20/99 500lbs seed destroyed
97-273-08n	97-285XR	Final report submitted 10/20/99 disposition of seed will be obtained

1998

98-033-06n	98-040XR	Final report will be submitted
98-035-04n	98-042XR	Final report submitted All seed stored in Colorado final disposition to be obtained
98-075-12n	98-150XR	Trial not planted Final report to be faxed
98-075-25n	98-151XR	Final report prepared will fax
98-030-05n	98-035XR	Weld County site 281lbs seed shipped to Monsanto St. Louis destroyed, Pondera County, MT and North Central station incinerated.
98-035-02n	98-041XR	Ward County, ND; Weld County, CO; & Walla Walla County, WA were never planted. Pondera County, MT - all seed destroyed, spread over plot and sprayed with herbicide.
98-224-03n	98-313XR	Sedgwick County, KS 150 pounds seed returned to Monsanto in St. Louis County, MO - distributed to three states; CO, MT, WA - 23 pounds each - remaining seed at Monsanto in St. Louis County, MO. Seeds from Chase County, NE were burned.

1/30/98 2:43 pm

Notification Tracking Sheet

=====

Bp number: 98-030-05n

=====

App number: 98-035XR
Received: 1/30/98
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/01/98
Phenotype: HT - Glyphosate tolerant
Comments:

Begin movement:
End movement:
Begin release: 2/28/98
End release: 2/28/99
Acre: 15.00
CBI status: CBI

Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Fax: 314-737-7085

=====

- | | Initial | Date |
|--|---------|-------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [2/2/98] |
| 2. <input type="checkbox"/> Review by biotechnologist | []* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed Ex | [EDH] | [2-2-98]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Release	*	*CO	*	1*WR	*	[]
Release	*	*MN	*	1*NER	*	[]
Release	*	*MT	*	1*WR	*	[]
Release	*	*ND	*	1*SCR	*	[]
Release	*	*WA	*	1*WR	*	[]

- | | | |
|--|---------|-------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [2/2/98] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [] | [3/5/98]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [bgs] | [3/6/98] |

CONTAINS CBI

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

January 28, 1998

Ms. E. Dianne Hatmaker
Animal and Plant Health Inspection Service
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, Maryland 20737-1237

1. Reference Number:

98-030-05n

2. Applicant Reference Number: 98-035XR

3. Applicant/Responsible party:

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

(b) (6), (b) (7)(C)

Tel: (b) (6), (b) (7)(C)

Fax: 314/737-7085

4. Duration of Introduction:

Release: February 28, 1998 - February 28, 1999

5. Recipient: Wheat, *Triticum aestivum*,, cultivar Bobwhite

CONTAINS CBI

Notification 98-035XR

January 28, 1998

Page 2

6. Regulated Article:

designation of transformed lines: 24756, 26248category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT04gene of interest

CBI

CMoVa/I2 -

(b) (4)

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CBI

CMP 3/I5

(b) (4)

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CONTAINS CBI

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designation of transformed lines: 25372, 25397, 25463category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT05gene of interest

CBI CMoVa/I5

(b) (4)

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CBI CMP 3/I5

(b) (4)

(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species..

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CONTAINS CBI

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designation of transformed lines: 26281, 27249category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT06gene of interest

CBI CMoVa/I5+leader2 (b) (4)
(b) (4)

CBI CTP2-HMEsyn - (b) (4)
(b) (4)

CBI M1 3' (b) (4)
(b) (4)

gene of interest

CBI CMoVa/I5+leader1 (b) (4)
(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI M1 3' (b) (4)
(b) (4)

CONTAINS CBI

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Page 5

Construct Description for PV-TXGT06 (Cont'd)gene of interest

CBI CMoVa/I2 - (b) (4)
(b) (4)

CBI CTP1-GME_{syn} (b) (4)
(b) (4)

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CONTAINS CBI

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designation of transformed lines: 25462, 28204category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT07gene of interest

CBI CMoVa/15 (b) (4)
(b) (4)

CBI CTP2-HMEsyn (b) (4)
(b) (4)

CBI M1 3 (b) (4)
(b) (4)

gene of interest

CBI CMoVa/15+leader2 (b) (4)
(b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI M1 3 (b) (4)
(b) (4)

CONTAINS CBI

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January 28, 1998

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Construct Description for PV-TXGT07 (Cont'd)gene of interest

CBI CMoVa/I2 - (b) (4)
(b) (4)

CBI CTP1-GMEsyn (b) (4)
(b) (4)

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CONTAINS CBI

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designation of transformed lines: 28598category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT09gene of interest

CBI CMP 3/I5 (b) (4)

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CBI CMoVa/I2 - (b) (4)

CBI CTP1-GMEsyn (b) (4)

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CONTAINS CBI

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Construct Description for PV-TXGT09 (Cont'd)gene of interestCBI CMoV_a/IS

(b) (4)

(b) (4)

CBI CTP2-PME_{syn} -

(b) (4)

(b) (4)

CBI M1 3'

(b) (4)

(b) (4)

CONTAINS CBI

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January 28, 1998

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designation of transformed lines: 1121category: HTphenotype: glyphosate tolerantconstruct: PV-TXSM09gene of interest

CBI CMP1/[12] (b) (4)

(b) (4)

CBI CTP4-CP4 (b) (4)

(b) (4)

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

Monsanto

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Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

7. Mode of Transformation: particle gun

8. Introduction:

Release:

NUMBER OF STATES/TERRITORIES AND SITES: CO(1), MN(1), MT(1), ND(1), WA(1)

(b) (4) Weld County, CO, (b) (4), (b) (6), (b) (7)(C) up to 3 acres.

(b) (4), (b) (6), (b) (7)(C) Clay County, MN, up to 3 acres.

(b) (4) Fondera County, MT, (b) (4), (b) (6), (b) (7)(C) up to 3 acres.

(b) (4) Ward County, ND, (b) (4), (b) (6), (b) (7)(C) up to 3 acres.

Monsanto Pacific Northwest Agriculture Center, Walla Walla County, WA, (b) (4), (b) (6), (b) (7)(C) up to 3 acres.

9. Certification: I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

January 28, 1998

(b) (6), (b) (7)(C)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

CBI Justification
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Page 2

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

CBI Justification
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Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

CBI Justification
Notification 98-035XR
Page 4

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

<u>Page</u>	<u>Category of Information</u>	<u>Justification</u>
2	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_012088

CBI Justification
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Page 5

- | | | |
|----|--------------------------------|--|
| 5 | Description of Genes/Promoters | See discussion on gene description - names and information about genes, promoters, and expressed traits. |
| 6 | Description of Genes/Promoters | See discussion on gene description - names and information about genes, promoters, and expressed traits. |
| 7 | Description of Genes/Promoters | See discussion on gene description - names and information about genes, promoters, and expressed traits. |
| 8 | Description of Genes/Promoters | See discussion on gene description - names and information about genes, promoters, and expressed traits. |
| 9 | Description of Genes/Promoters | See discussion on gene description - names and information about genes, promoters, and expressed traits. |
| 10 | Description of Genes/Promoters | See discussion on gene description - names and information about genes, promoters, and expressed traits. |

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

facsimile transmittal

To: Ms E. Dianne Hatmaker

Fax: 301/734-8910

From: (b) (6), (b) (7)(C)

Date: January 29, 1998

Re: 98-035XR

Pages: 28

CC: [Click here and type name]

Xquick review ☐ For Review

☐ Please Comment

☐ Please Reply

☐ Please Recycle

Notes

Submitting for approval.

OR120018_BR_012090

CBI DELETED

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

January 28, 1998

Ms. E. Dianne Hatmaker
Animal and Plant Health Inspection Service
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, Maryland 20737-1237

1. Reference Number: 98-030-05n
2. Applicant Reference Number: 98-035XR
3. Applicant/Responsible party:

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

(b) (6), (b) (7)(C)
Tel: (b) (6), (b) (7)(C)
Fax: 314/737-7085

4. Duration of Introduction:

Release: February 28, 1998 - February 28, 1999

5. Recipient: Wheat, *Triticum aestivum*., cultivar Bobwhite

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 2

6. Regulated Article:

designation of transformed lines: 24756, 26248category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT04gene of interest

CBI CMoVa/I2 - [

]

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CBI CMP 3/I5 [

]

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 3

designation of transformed lines: 25372, 25397, 25463category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT05gene of interest

CBI CMoVa/I5 I

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CMP 3/I5 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI I I

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species..

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 4

designation of transformed lines: 26281, 27249category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT06gene of interest

CBI CMoVa/I5+Header2 |

|

CBI CTP2-HMEsyn -|

|

CBI M1 3' |

|

gene of interest

CBI CMoVa/I5+Header1 |

|

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI M1 3' |

|

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 5

Construct Description for PV-TXGT06 (Cont'd)gene of interest**CBI** CMoVa/I2 - [

]

CBI CTP1-GMEsyn [

]

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

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Page 6

designation of transformed lines: 25462, 28204category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT07gene of interest

CBI CMoVa/I5 [

]

CBI CTP2-HMEsyn -[

]

CBI M1 3' [

]

gene of interest

CBI CMoVa/I5+leader2 [

]

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI M1 3' [

]

CBI DELETED

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January 28, 1998
Page 7

Construct Description for PV-TXGT07 (Cont'd)gene of interest

CBI CMoVa/I2 - [

|

CBI CTP1-GMEsyn[

|

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 8

designation of transformed lines: 28579category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT09gene of interest

CBI CMP 3/I5 [

]

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CBI CMoVa/I2 - [

]

CBI CTP1-GMEsyn [

]

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 9

Construct Description for PV-TXGT09 (Cont'd)gene of interest

CBI CMoVa/15 |

]

CBI CTP2-PMESyn - |

]

CBI M1 3' [

]

CBI DELETED

Notification 98-035XR
January 28, 1998
Page 10

designation of transformed lines: 1121

category: HT

phenotype: glyphosate tolerant

construct: PV-TXSM09

gene of interest

CBI CMP1/[I2] |

|

CBI CTP4-CP4|

|

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

Notification 98-035XR
January 28, 1998
Page 11

7. Mode of Transformation: particle gum

8. Introduction:

Release:

NUMBER OF STATES/TERRITORIES AND SITES: CO(1), MN(1), MT(1), ND(1), WA(1)

(b) (7)(C) Weld County, CO, (b) (6), (b) (7)(C), (b) (4) up to 3 acres.

(b) (6), (b) (7)(C), (b) (4) Clay County, MN, up to 3 acres.

(b) (7)(C) Pondera County, MT, (b) (6), (b) (7)(C), (b) (4) up to 3 acres.

(b) (7)(C) Ward County, ND, (b) (6), (b) (7)(C), (b) (4) up to 3 acres.

(b) (7)(C) Walla Walla County, WA, (b) (6), (b) (7)(C), (b) (4) up to 3 acres.

9. Certification: I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

January 28, 1998

(b) (6), (b) (7)(C)

CBI DELETED

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

January 28, 1998

Ms. E. Dianne Hatmaker
Animal and Plant Health Inspection Service
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, Maryland 20737-1237

1. **Reference Number:** 98-030-05n
2. **Applicant Reference Number:** 98-035XR
3. **Applicant/Responsible party:**

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

(b) (6), (b) (7)(C)
Tel: (b) (6), (b) (7)(C)
Fax: 314/737-7085

4. **Duration of Introduction:**

Release: February 28, 1998 - February 28, 1999

5. **Recipient:** Wheat, *Triticum aestivum*, cultivar Bobwhite

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 2

6. **Regulated Article:**designation of transformed lines: 24756, 26248category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT04gene of interest

CBI CMoVa/I2 - [

]

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CBI CMP 3/I5 [

]

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR
January 28, 1998
Page 3

designation of transformed lines: 25372, 25397, 25463

category: HT

phenotype: glyphosate tolerant

construct: PV-TXGT05

gene of interest

CBI CMoVa/15 |

|

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CMP 3/15 - The CMP3 (constitutive promoter 3) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI |

|

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species..

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 4

designation of transformed lines: 26281, 27249category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT06gene of interest

CBI CMoVa/15+Header2 |

CBI CTP2-HMEsyn -[

CBI M1 3' |

gene of interest

CBI CMoVa/15+header1 |

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI M1 3' |

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 5

Construct Description for PV-TXGT06 (Cont'd)gene of interest

CBI CMoVa/I2 - [

]

CBI CTP1-GMEsyn [

]

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 6

designation of transformed lines: 25462, 28204category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT07gene of interest

CBI CMoVa/I5 [

|

CBI CTP2-HMEsyn -[

|

CBI M1 3' [

|

gene of interest

CBI CMoVa/I5+leader2 [

|

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

CBI M1 3' [

]

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 7

Construct Description for PV-TXGT07 (Cont'd)gene of interest

CBI CMoVa/I2 - [

]

CBI CTP1-GMEsyn[

]

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 8

designation of transformed lines: 28579category: HTphenotype: glyphosate tolerantconstruct: PV-TXGT09gene of interest

CBI CMP 3/I5 [

]

CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

gene of interest

CBI CMoVa/I2 - [

]

CBI CTP1-GMEsyn [

]

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 9

Construct Description for PV-TXGT09 (Cont'd)gene of interest

CBI CMoVa/IS |

]

CBI CTP2-PMEsyn - |

]

CBI M1 3' |

]

CBI DELETED

Notification 98-035XR

January 28, 1998

Page 10

designation of transformed lines: 1121category: HTphenotype: glyphosate tolerantconstruct: PV-TXSM09gene of interest

CBI CMP1/[I2] |

CBI CTP4-CP4|

NOS 3' A 3' non-translated region of the nopaline synthase gene which functions to direct polyadenylation of the mRNA.

OR120018_BR_012111

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone (314) 694-1000

Notification 98-035XR
January 28, 1998
Page 11

7. Mode of Transformation: particle gun

8. Introduction:

Release:

NUMBER OF STATES/TERRITORIES AND SITES: CO(1), MN(1), MT(1), ND(1), WA(1)

(b) (4) Weld County, CO, (b) (6), (b) (7)(C), (b) (4) up to 3 acres.

(b) (6), (b) (7)(C), (b) (4) Clay County, MN, up to 3 acres.

(b) (4) Pondera County, MT, (b) (6), (b) (7)(C), (b) (4) up to 3 acres.

(b) (4) Ward County, ND, (b) (6), (b) (7)(C), (b) (4) up to 3 acres.

(b) (4) Walla Walla County, WA, (b) (6), (b) (7)(C), (b) (4) up to 3 acres.

9. **Certification:** I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C) January 28, 1998

file copy

Mr. Leslie A. Zermuehlen
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

January 30, 1998

Dear Mr. Zermuehlen:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012113

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 30, 1998

Dear Dr. Hanks:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: J. Burch, PPQ, Pickerington, OH

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012114

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 30, 1998

Dear Dr. Gingery:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012115

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 30, 1998

Dear Mr. Nelson:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012116

file copy

Mr. Thomas L. Wessels, State Pathologist
Plant Services Division
Washington Department of Agriculture
24106 N. Bunn Road
Prosser, WA 99350

January 30, 1998

Dear Mr. Wessels:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012117



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Leslie A. Zermuehlen
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

COLD. DEPT.
RECEIVED
FEB 03 1998
OF AGRICULTURE
PLANT AND INSECT SECTION

January 30, 1998

Dear Mr. Zermuehlen:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

B. Diane Batmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Leslie A. Zermuehlen

Signature: (b) (6), (b) (7)(C)

Date: February 6, 1998

State: Colorado



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OR120018_BR_012118



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Beverdale, MD 20737

forwarded 2-26-98

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 30, 1998

Dear Dr. Hanks:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: J. Burch, PPQ, Pickerington, OH

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: **(b) (6), (b) (7)(C)**

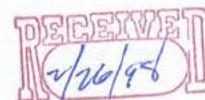
Date: 2-26-98

State: MN



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OR120018_BR_012119



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 30, 1998

TSB
Shaw
hawaii
ggg

Dear Dr. Gingery:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

L. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbra Mullin

Signature: (b) (6), (b) (7)(C)

Date: 6 Feb-98

State: MONTANA





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverside, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 30, 1998

Dear Mr. Nelson:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 98-030-05n Applicant #: 98-035XR
Received: January 30, 1998 Effective: March 1, 1998
Institution: Monsanto Recipient: Wheat
Interstate destination:
Release destination: CO MN MT ND WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID NELSON

Signature: (b) (6), (b) (7)(C)

Date: 2/12/98

State: ND



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OR120018_BR_012121



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, State Pathologist
Plant Services Division
Washington Department of Agriculture
24106 N. Sunn Road
Prosser, WA 99350

January 30, 1998

Dear Mr. Wessels:

Enclosed is notification 98-030-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-030-05n	Applicant #:	98-035XR
Received:	January 30, 1998	Effective:	March 1, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MN MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Thomas L. Wessels*

Signature: *(b) (6), (b) (7)(C)*

Date: *2/17/98*

State: *WA*



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An Equal Opportunity Employer

OR120018_BR_012122

ENTERED

March 5, 1998

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request number (98-035XR) 98-030-05N, requesting permission to move interstate the regulated article wheat, under 7 CFR 340.3 (c) is acknowledged. The notification will become effective and may be executed on or after March 5, 1998.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Operations Officers.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology and Scientific Evaluations
Plant Protection and Quarantine

Enclosure

cc:

L. Zermuehlen, Colorado Dept. of Agric., Lakewood, CO
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
G. Gingery, Montana Dept. of Agric., Helena, MT
D. North Dakota Dept. of Agric., Bismarck, ND
T. Wessels, Washington Dept. of Agric., Prosser, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Brownsville, TX
J. Burch, PPQ, NER, Pickerington, OH
File number 98-030-05N

OR120018_BR_012123

FINAL REPORT
1998
Wheat

(b) (6), (b) (7)(C)

Monsanto Company

USDA Ref. # 98-030-05n	Monsanto Ref. # 98-035XR

<u>Site Locations</u>	<u>County & State</u>
<div style="font-size: 4em; color: red; font-weight: bold;">(b) (4)</div>	Pondera County MT
	Walla Walla, WA
	Weld County, CO
	Ward County, ND

County/State

Planting Date; N.D. 5/29/98, MT, 5/11/98 and 5/26/98, WA, 4/3/98, CO 3/98

Harvest/Destruct Date & Method: WA 8/11/98, N.D. 9/3/98, CO 8/5/98 MT 9/2/98

Vector Constructs/Line Numbers Planted: line number 24756, 26248, 25372, 25397, 25463, 26281, 27249, 25462, 28204, 28579, 1121

Purpose/Objective:

Field Monitoring for Disease Susceptibility

Field Monitoring for Insect Susceptibility

Field Monitoring for Plant Growth Characteristics

Field Monitoring for Weediness Characteristics

Field Monitoring for Plant Stand

Monitoring for Volunteer Plants

This field trial was monitored, throughout the growing season for insect and disease susceptibility, and plant growth and weediness characteristics. This field trial does not pose a plant pest risk to the unmodified recipient organism from which it was derived.

OR120018_BR_012124

apl
11/22/99

FAX

Date: 12/08/1999

Number of pages including cover sheet: _____

To:Ms. Susan KoehlerUSDA - APHISPhone:Fax phone:CC:**From:**(b) (6), (b) (7)(C)Monsanto Company700 Chesterfield Parkway NorthSt. Louis, MO 63198Phone:Fax phone: (636) 737-7085**REMARKS:**

Urgent



For your review



Reply ASAP



Please comment

Dear Ms. Koehler,

Per your request, I am attaching the status of Monsanto wheat trials and seed disposition. At this time, we are continuing to gather information on the final disposition of some of the material.

I will be in contact with you tomorrow regarding this matter.

Regards,

(b) (6), (b) (7)(C)

WHEAT TRIALS

1997

USDA #	Monsanto #	Status
97-275-03n	97-281XR	Final report submitted 10/20/99 1500lbs seed yield all destroyed in Yuma, AZ
97-289-05n	97-312XRAB	Final report submitted 10/20/99 150lbs seed all destroyed in Yuma, AZ
97-289-06n	97-313XRAB	Final report submitted 10/20/99 1500lbs seed destroyed in Yuma, AZ
97-289-07n	97-314XRAB	Final report submitted 10/20/99 500lbs seed destroyed in Yuma, AZ
97-289-08n	97-315XRAB	Final report submitted 10/20/99 500lbs seed destroyed
97-273-08n	97-285XR	Final report submitted 10/20/99 disposition of seed will be obtained

1998

98-033-06n	98-040XR	Final report will be submitted
98-035-04n	98-042XR	Final report submitted All seed stored in Colorado final disposition to be obtained
98-075-12n	98-150XR	Trial not planted Final report to be faxed
98-075-25n	98-151XR	Final report prepared will fax
98-030-05n	98-035XR	Weld County site 281lbs seed shipped to Monsanto St. Louis destroyed, Pondera County, MT and North Central station incinerated.
98-035-02n	98-041XR	Ward County, ND; Weld County, CO; & Walla Walla County, WA were never planted. Pondera County, MT - all seed destroyed, spread over plot and sprayed with herbicide.
98-224-03n	98-313XR	Sedgwick County, KS 150 pounds seed returned to Monsanto in St. Louis County, MO - distributed to three states; CO, MT, WA - 23 pounds each - remaining seed at Monsanto in St. Louis County, MO. Seeds from Chase County, NE were burned.

2/05/98 12:12 pm

Notification Tracking Sheet

=====

Bp number: 98-035-02n

=====

App number: 98-041XR
Received: 2/04/98
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/06/98
Phenotype: HT - Glyphosate tolerant
Comments:

Begin movement:
End movement:
Begin release: 3/05/98
End release: 3/05/99
Acre: 12.00
CBI status: CBI

Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C) (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Fax: 314-737-7085

- | | Initial | Date |
|--|----------|-------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [aip] | [2/5/98] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [DSH]* | [2/5/98]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed Ex | [odt] | [2-6-98]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Release	*	*CO	*	1*WR	*	[]
Release	*	*MT	*	1*WR	*	[]
Release	*	*ND	*	1*SCR	*	[]
Release	*	*WA	*	1*WR	*	[]

- | | | |
|---|---------|-------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [aip] | [2/5/98] |
| 6. <input type="checkbox"/> Letter of acknowledgement/denial/withdraw | [] | [3/2/98]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [bgs] | [3/5/98] |

OK
~~INCOMPLETE DONOR INFORMATION~~

Monsanto

CONFIDENTIAL

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

Monsanto Reference ID
98-041XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

03-Feb-98

98-035-02n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

98-041XR

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)

700 Chesterfield Village Pkwy

St. Louis, MO 63198

4. Duration of Introduction

Release

3/5/98 - 3/5/99

5. Recipient Wheat, Triticum aestivum
6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate-tolerant

CONFIDENTIAL

designation of transformed line: 31136, 31137, 31152

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [REDACTED] (b) (4)
[REDACTED] - CBI
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens.

Gene of Interest

- * Promoter: CMoVa/I2 -- [REDACTED] (b) (4)
[REDACTED]
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens.

Monsanto Reference ID
98-041XR

CONFIDENTIAL

designation of transformed line: 30653, 30671, 30672, 30677, 30681, 31124

Constructs: PV-TXGT11

genotype:

Gene of Interest

- * Promoter: CMOVa/I4 -- A caulimovirus promoter plus intron with the duplicated enhancer region.
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: M1 3' -- [(b) (4)]

[REDACTED]

CBI

Gene of Interest

- * Promoter: CMP3/I5 + leader 2 -- [(b) (4)]
- [REDACTED]
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: NOS 3' +2 -- [(b) (4)]

[REDACTED]

CBI

CONFIDENTIAL

7. Mode of Transformation

Disarmed *Agrobacterium tumefaciens*

8. Introduction

Release

Release Sites:

* [REDACTED] (b) (4), Weld County, Colorado, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Ward County, North Dakota, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Pondera County, Montana, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4) Walla Walla County, Washington, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Monsanto

~~CONFIDENTIAL~~

9. Certification

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 691-1000

I certify that the regulated article ~~will be introduced~~ in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
03-Feb-98

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

<u>Page</u>	<u>Category of Information</u>	<u>Justification</u>
2	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Genes/Promoters	See discussion on gene description - names and information about genes, promoters, and expressed traits.

CBI DELETED

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

Monsanto Reference ID
98-041XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

03-Feb-98

98-035-02n

1. USDA Reference Number

2. Applicant Reference Number

98-041XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Release

3/5/98 - 3/5/99

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate-tolerant

Monsanto Reference ID
98-041XR

designation of transformed line: 31136, 31137, 31152

Constructs: PV-TXGT10
genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens.

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens.

designation of transformed line: 30653, 30671, 30672, 30677, 30681, 31124

Constructs: PV-TXGT11
genotype:

Gene of Interest

- * Promoter: CMoVa/I4 -- A caulimovirus promoter plus intron with the duplicated enhancer region.
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: M1 3' -- [CBI Deleted]

CBI DELETED

Monsanto Reference ID
98-041XR

- * Promoter: CMP3/I5 + leader 2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.
- * Terminator: NOS 3' +2 -- [CBI Deleted]

CBI DELETED

Monsanto Reference ID
98-041XR

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Release

Release Sites:

* [REDACTED] (b) (4), Weld County, Colorado, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Ward County, North Dakota, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Pondera County, Montana, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Walla Walla County, Washington, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4),
(b) (6), (b) (7)(C), (b) (4)

Monsanto Reference ID
98-041XR

Monsanto

9. Certification

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
03-Feb-98

CBI DELETED

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

Monsanto Reference ID
98-041XR

Permit Unit
USDA, APHIS, PPQ, BSS
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Riverdale, MD 20737

03-Feb-98

98-035-02n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

98-041XR

(b) (6), (b) (7)(C)

Phone

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FAX

314-737-7085

Monsanto Company

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Release

3/5/98 - 3/5/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate-tolerant

Monsanto Reference ID
98-041XR

designation of transformed line: 31136, 31137, 31152

Constructs: PV-TXGT10
genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens.

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens.

designation of transformed line: 30653, 30671, 30672, 30677, 30681, 31124

Constructs: PV-TXGT11
genotype:

Gene of Interest

- * Promoter: CMoVa/I4 -- A caulimovirus promoter plus intron with the duplicated enhancer region.
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species.
- * Terminator: M1 3' -- [CBI Deleted]

CBI DELETED

Monsanto Reference ID
98-041XR

- * Promoter: CMP3/15 + leader 2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- CTP2-CP4 is a gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species.
- * Terminator: NOS 3' +2 -- [CBI Deleted]

CBI DELETED

Monsanto Reference ID
98-041XR

7. Mode of Transformation

Disarmed *Agrobacterium tumefaciens*

8. Introduction

Release

Release Sites:

* [REDACTED] (b) (4), Weld County, Colorado, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Ward County, North Dakota, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Pondera County, Montana, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

* [REDACTED] (b) (4), Walla Walla County, Washington, 3 acres. Contact: (b) (6), (b) (7)(C), (b) (4)

Monsanto Reference ID
98-041XR

Monsanto

9. Certification

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
03-Feb-98

file copy

Mr. Leslie A. Zermuehlen
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 5, 1998

Dear Mr. Zermuehlen:

Enclosed is notification 98-035-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-035-02n	Applicant #:	98-041XR
Received:	February 4, 1998	Effective:	March 6, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012147

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 5, 1998

Dear Dr. Gingery:

Enclosed is notification 98-035-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-035-02n	Applicant #:	98-041XR
Received:	February 4, 1998	Effective:	March 6, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012148

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 5, 1998

Dear Mr. Nelson:

Enclosed is notification 98-035-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-035-02n	Applicant #:	98-041XR
Received:	February 4, 1998	Effective:	March 6, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012149

file copy

Mr. Thomas L. Wessels, State Pathologist
Plant Services Division
Washington Department of Agriculture
24106 N. Bunn Road
Prosser, WA 99350

February 5, 1998

Dear Mr. Wessels:

Enclosed is notification 98-035-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-035-02n	Applicant #:	98-041XR
Received:	February 4, 1998	Effective:	March 6, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012150



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Plant Protection and Quarantine
Biotechnology and Scientific Services
4700 River Road, Unit 145
Riverdale, MD 20737-1236

RECEIVED

031 21 831

FEB 18 1998

Mr. Leslie A. Zermuehlen
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 5, 1998

Dear Mr. Zermuehlen:

Enclosed is notification 98-035-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-035-02n	Applicant #:	98-041XR
Received:	February 4, 1998	Effective:	March 6, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Leslie A. Zermuehlen

Signature:

(b) (6), (b) (7)(C)

Date: February 18, 1998

State: Colorado



APHIS - Protecting American Agriculture
Phone: (301) 734-7602, FAX (301) 734-3643

An Equal Opportunity Employer

OR120018_BR_012151

RECEIVED
2/18/98



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 5, 1998

Dear Dr. Gingery:

Enclosed is notification 98-035-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-035-02n	Applicant #:	98-041XR
Received:	February 4, 1998	Effective:	March 6, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbra Mullin

Signature: (b) (6), (b) (7)(C)

Date: 10 Feb 98

State: Montana





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20712



February 5, 1998

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

Dear Mr. Nelson:

Enclosed is notification 98-035-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 98-035-02n Applicant #: 98-041XR
Received: February 4, 1998 Effective: March 6, 1998
Institution: Monsanto Recipient: Wheat
Interstate destination:
Release destination: CO MT ND WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

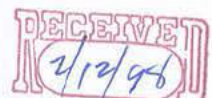
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID NELSON

Signature: (b) (6), (b) (7)(C)

Date: 2/11/98

State: ND



APHIS • Promoting American Agriculture

OR120018_BR_012453

Animal and Plant Health Inspection Service



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wassels, State Pathologist
Plant Services Division
Washington Department of Agriculture
24106 N. Bunn Road
Prosser, WA 99350

February 5, 1998

Dear Mr. Wassels:

Enclosed is notification 98-035-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-035-02n	Applicant #:	98-041XR
Received:	February 4, 1998	Effective:	March 6, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	CO MT ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wassels

Signature: (b) (6), (b) (7)(C)

Date: 2/17/98

State: WA



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_012154

ENTERED

March 2, 1998

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request number (98-041XR) 98-035-02N, requesting permission to release into the environment the regulated article wheat, under 7 CFR 340.3 (c) is acknowledged. The notification will become effective and may be executed on or after March 6, 1998.

This acknowledgment does not authorize use of "challenge organisms" for field test.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Operations Officers.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology and Scientific Evaluations
Plant Protection and Quarantine

Enclosure

cc:

L. Zermuehlen, Colorado Dept. of Agric., Lakewood, CO
G. Gingery, Montana Dept. of Agric., Helena, MT
D. North Dakota Dept. of Agric., Bismarck, ND
T. Wessels, Washington Dept. of Agric., Prosser, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Brownsville, TX
File number 98-035-02N

OR120018_BR_012155

Monsanto Company

700 Chesterfield Parkway North, St. Louis, Missouri 63198,

Mail Code BB1K

FAX

Date: 12/08/1999

Number of pages including cover sheet:

To:

Ms. Susan Koehler

USDA - APHIS

Phone:

Fax phone:

CC:

From:

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis, MO 63198

Phone:

(b) (6), (b) (7)(C)

Fax phone:

(636) 737-7085

REMARKS:

☒ Urgent

☐ For your review

☐ Reply ASAP

☐ Please comment

Dear Ms. Koehler,

Per your request, I am attaching the status of Monsanto wheat trials and seed disposition. At this time, we are continuing to gather information on the final disposition of some of the material.

I will be in contact with you tomorrow regarding this matter.

Regards,

(b) (6), (b) (7)(C)

OR120018_BR_012156

WHEAT TRIALS

1997

USDA #	Monsanto #	Status
97-275-03n	97-281XR	Final report submitted 10/20/99 1500lbs seed yield all destroyed in Yuma, AZ
97-289-05n	97-312XRAB	Final report submitted 10/20/99 150lbs seed all destroyed in Yuma, AZ
97-289-06n	97-313XRAB	Final report submitted 10/20/99 1500lbs seed destroyed in Yuma, AZ
97-289-07n	97-314XRAB	Final report submitted 10/20/99 500lbs seed destroyed in Yuma, AZ
97-289-08n	97-315XRAB	Final report submitted 10/20/99 500lbs seed destroyed
97-273-08n	97-285XR	Final report submitted 10/20/99 disposition of seed will be obtained

1998

98-033-06n	98-040XR	Final report will be submitted
98-035-04n	98-042XR	Final report submitted All seed stored in Colorado final disposition to be obtained
98-075-12n	98-150XR	Trial not planted Final report to be faxed
98-075-25n	98-151XR	Final report prepared will fax
98-030-05n	98-035XR	Weld County site 281lbs seed shipped to Monsanto St. Louis destroyed, Pondera County, MT and North Central station incinerated.
98-035-02n	98-041XR	Ward County, ND; Weld County, CO; & Walla Walla County, WA were never planted. Pondera County, MT - all seed destroyed, spread over plot and sprayed with herbicide.
98-224-03n	98-313XR	Sedgwick County, KS 150 pounds seed returned to Monsanto in St. Louis County, MO - distributed to three states; CO, MT, WA - 23 pounds each - remaining seed at Monsanto in St. Louis County, MO. Seeds from Chase County, NE were burned.

FINAL REPORT
1998
Wheat

(b) (6), (b) (7)(C)
Monsanto Company

USDA Ref. # 98-035-02n

Monsanto Ref. # 98-041XR

Site Locations

(b) (4)

County & State

Weld County, CO (not planted)

Ward County, ND (not planted)

Walla Walla, WA (not planted)

Pontera County, Montana

County/State

Planting Date; 5/11/98; 5/26/98

Harvest/Destruct Date & Method: 9/2/98

Vector Constructs/Line Numbers Planted: PV-TXGT10, 31136, 31137, 31152

Purpose/Objective:

Field Monitoring for Disease Susceptibility

Field Monitoring for Insect Susceptibility

Field Monitoring for Plant Growth Characteristics

Field Monitoring for Weediness Characteristics

Field Monitoring for Plant Stand

Monitoring for Volunteer Plants

This field trial was monitored, throughout the growing season for insect and disease susceptibility, and plant growth and weediness characteristics. This field trial does not pose a plant pest risk to the unmodified receipt organism from which it was derived.

OR120018_BR_012158

FINAL REPORT

1998

Wheat

(b) (6), (b) (7)(C)

Monsanto Company

USDA Ref. # 98-035-02n

Monsanto Ref. # 98-041XR

Site Locations

County & State

(b) (4)

Weld County, CO (never planted)

Ward County, N.D.

Pondera County, CO

Walla Walla County, (never planted)

Not correct
per

(b) (6), (b) (7)(C)

12/9/99,
only MT
was
planted

County/State

Planting Date; MT 5/11/98, 5/26/98 N.D. 5/29/98

Harvest/Destruct Date & Method: MT. 9/2/98 N.D. 9/3/98

Vector Constructs/Line Numbers Planted: line 31136, 31137, 31152, 30653, 30671, 30672, 30677, 30681, 31142

Purpose/Objective:

Field Monitoring for Disease Susceptibility

Field Monitoring for Insect Susceptibility

Field Monitoring for Plant Growth Characteristics

Field Monitoring for Weediness Characteristics

Field Monitoring for Plant Stand

Monitoring for Volunteer Plants

This field trial was monitored, throughout the growing season for insect and disease susceptibility, and plant growth and weediness characteristics. This field trial does not pose a plant pest risk to the unmodified recipient organism from which it was derived.

OR120018_BR_012159

ajal
11/22/99

8/13/98 11:17 am

Notification Tracking Sheet

Bp number: 98-224-03n

App number: 98-313XR
Received: 8/12/98
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 9/11/98
Phenotype: HT - Glyphosate tolerant

Begin movement:
End movement:
Begin release: 9/08/98
End release: 9/08/99
Acre: 2.00
CBI status: CBI

Comments:

Resp person: (b) (6), (b) (7)(C)

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway North

Address3:

Address4:

City/State/Zip: St. Louis, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax: 314-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ajd]	[8/13/98]
2. <input type="checkbox"/> Review by biotechnologist	[dn]*	[]*
3. <input checked="" type="checkbox"/> Letter of notification to State	[KZw]	[8/17/98]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg
Release	*	*KS	*	1*SCR *
Release	*	*NE	*	1*SCR *

5. <input checked="" type="checkbox"/> Enter genes into database	[ajd]	[8/13/98]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[KZw]	[9/15/98]*
7. <input checked="" type="checkbox"/> Enter final data into database	[KZw]	[9/15/98]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

Monsanto Reference ID
98-313XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

09-Aug-98

98-224-03n

1. **USDA Reference Number**
2. **Applicant Reference Number**
3. **Applicant/Responsible Party**

98-313XR

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy
St. Louis, MO 63198

4. Duration of Introduction

Release

9/8/98 - 9/8/99

5. **Recipient** Wheat, Triticum aestivum
6. **Regulated Article**

Phenotypic Category: HT

Phenotype glyphosate tolerant

Cultivar: B1175, AC Barrie and Bobwhite Progeny

CONFIDENTIAL

Monsanto Reference ID
98-313XR

designation of transformed line: 25372, 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)

(b) (4)

- CBI

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: TSP7 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
98-313XR

7. Mode of Transformation Particle Bombardment

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

KS(1)

NE(1)

KS

(b) (4) CO. Contact: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Sedgwick County, KS up to 1 acres.

NE

* (b) (4) CO. Contact: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Chase County, NE up to 1 acres.

MONSANTO

Food • Health • Hope



CONFIDENTIAL

Monsanto Reference ID
98-313XR

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

09-Aug-98

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
98-313XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

09-Aug-98

98-224-03n

1. USDA Reference Number

2. Applicant Reference Number 98-313XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Release

9/8/98 - 9/8/99

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype glyphosate tolerant

Cultivar: B1175, AC Barrie and Bobwhite Progeny

Monsanto Reference ID
98-313XR

designation of transformed line: 25372, 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: TSP7 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI DELETED

Monsanto Reference ID
98-313XR

7. **Mode of Transformation** Particle Bombardment

8. **Introduction** Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

KS(1)

NE(1)

KS

* (b) (4) CO. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Sedgwick County, KS up to 1 acres.

NE

* (b) (4) CO. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Chase County, NE up to 1 acres.

Monsanto Reference ID
98-313XR



~~MONSANTO COMPANY~~
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
09-Aug-98



MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
98-313XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

09-Aug-98

98-224-03n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

98-313XR

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

4. Duration of Introduction

Release

9/8/98 - 9/8/99

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype glyphosate tolerant

Cultivar: B1175, AC Barrie and Bobwhite Progeny

Monsanto Reference ID
98-313XR

designation of transformed line: 25372, 25397

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: TSP7 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-313XR

7. Mode of Transformation Particle Bombardment

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

KS(1)

NE(1)

KS

*

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

CO. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location

(b) (4)

Sedgwick County, KS up to 1 acres.

NE

*

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

CO. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location:

(b) (4)

Chase County, NE up to 1 acres.

Monsanto Reference ID
98-313XR



MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
09-Aug-98

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 13, 1998

Dear Mr. Sim IV:

Enclosed is notification 98-224-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-224-03n	Applicant #:	98-313XR
Received:	August 12, 1998	Effective:	September 11, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	KS NE		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012177

file copy

Mr. Stephen V. Johnson, State Entomologist
Bureau of Plant Industry
Nebraska Department of Agriculture
301 Centennial Mall South - 4th Floor
Lincoln, NE 68509-4756

August 13, 1998

Dear Mr. Johnson:

Enclosed is notification 98-224-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-224-03n	Applicant #:	98-313XR
Received:	August 12, 1998	Effective:	September 11, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	KS NE		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012178



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Sec
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

Post-it® Fax Note	7671	Date	# of pages 2
To	Dianne Hatake	From	Tom Sim
Co./Dept.	USA	Co.	Ks Dept. of Agr.
Phone #	301-734-5787	Phone #	785-246-6418
Fax #	301-734-8910	Fax #	785-246-6473

Dear Mr. Sim IV:

Enclosed is notification 98-224-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 98-224-03n

Applicant #: 98-313XR

Received: August 12, 1998

Effective: September 11, 1998

Institution: Monsanto

Recipient: Wheat

Interstate destination:

Release destination: KS NE

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatake, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 8/20/98

State: Kansas



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_012179

dup.

8/21/98



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Stephen V. Johnson, State Entomologist
Bureau of Plant Industry
Nebraska Department of Agriculture
301 Centennial Mall South - 4th Floor
Lincoln, NE 68509-4756

August 13, 1998

Dear Mr. Johnson:

Enclosed is notification 98-224-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number: 98-224-03n
Received: August 12, 1998
Institution: Monsanto
Interstate destination:
Release destination: KS NE

Applicant #: 98-313XR
Effective: September 11, 1998
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Stephen V. Johnson

Signature:

(b) (6), (b) (7)(C)

Date: 9/11/98

State: Nebraska



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OR120018_BR_012180

Confirmation Report-Memory Send

Time : 08-17-98 02:36pm
Tel line 1 : +3017348910
Tel line 2 : +
Name : USDA

Job number : 530
Date : 08-17 02:34pm
To : 919132960673
Document Pages : 05
Start time : 08-17 02:34pm
End time : 08-17 02:36pm
Pages sent : 05

Job number : 530

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

August 13, 1998

Dear Mr. Sim IV:

Enclosed is notification 98-224-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-224-03n	Applicant #:	98-313XR
Received:	August 12, 1998	Effective:	September 11, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	KS NE		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Diane Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_012181

Confirmation Report-Memory Send

Time : 08-17-98 02:06pm
Tel line 1 : +3017348910
Tel line 2 : +
Name : USDA

Job number : 527
Date : 08-17 02:05pm
To : 914024716892
Document Pages : 05
Start time : 08-17 02:05pm
End time : 08-17 02:06pm
Pages sent : 05
Job number : 527

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Stephen V. Johnson, State Entomologist
Bureau of Plant Industry
Nebraska Department of Agriculture
301 Centennial Mall South - 4th Floor
Lincoln, NE 68509-4756

August 13, 1998

Dear Mr. Johnson:

Enclosed is notification 98-224-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 98-224-03n
Received: August 12, 1998
Institution: Monsanto
Interstate destination:
Release destination: KS NE

Applicant #: 98-313XR
Effective: September 11, 1998
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature:

Date:

State:



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_012183

September 15, 1998

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after September 15, 1998.

Release

Notification no. 98-224-03n (98-313XR)

Regulated article - Wheat

Destination(s) - Kansas, Nebraska

This acknowledgment does not authorize use of "challenge organisms" for field test.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

State Regulatory Officials
D. DeWeese, PPQ, SCR, Brownsville, TX
File number 98-224-03n

OR120018_BR_012184

Ms. Anita Drummond
USDA, APHIS, PPQ
4700 River Road, Unit 147
Riverdale, MD 20737-1237

September 15, 1998

Dear Ms. Drummond,

REQUEST FOR COPIES OF NOTIFICATIONS

We would like to request courtesy, CBI-deleted copies, of the following notifications:

98-229-11n	98-229-02n	98-222-04n	98-215-03n
98-229-10n	98-229-01n	98-222-01n	98-215-02n
98-229-09n	98-226-01n	98-219-06n	98-215-01n
98-229-08n	98-225-02n	98-219-04n	98-208-01n
98-229-07n	98-225-01n	98-216-01n	98-202-01n
98-229-06n	98-224-03n	98-215-09n	98-201-08n
98-229-05n	98-223-03n	98-215-08n	98-194-01n
98-229-04n	98-223-01n	98-215-07n	98-183-01n
98-229-03n	98-222-05n	98-215-05n	98-161-02n

Thank you for your assistance and please do not hesitate to contact me at telephone (b) (6), (b) (7)(C) fax (302) 892-3099, with any questions or concerns regarding this request.

Sincerely,

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North, St. Louis, Missouri 63198,

Mail Code BB1K

FAX

Date: 12/08/1999

Number of pages including cover sheet: _____

To:

Ms. Susan Koehler

USDA - APHIS

Phone:

Fax phone:

CC:

From:

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis, MO 63198

Phone:

(b) (6), (b) (7)(C)

Fax phone:

(636) 737-7085

REMARKS:



Urgent



For your review



Reply ASAP



Please comment

Dear Ms. Koehler,

Per your request, I am attaching the status of Monsanto wheat trials and seed disposition. At this time, we are continuing to gather information on the final disposition of some of the material.

I will be in contact with you tomorrow regarding this matter.

Regards,

(b) (6), (b) (7)(C)

OR120018_BR_012186

WHEAT TRIALS

1997

USDA #	Monsanto #	Status
97-275-03n	97-281XR	Final report submitted 10/20/99 1500lbs seed yield all destroyed in Yuma, AZ
97-289-05n	97-312XRAB	Final report submitted 10/20/99 150lbs seed all destroyed in Yuma, AZ
97-289-06n	97-313XRAB	Final report submitted 10/20/99 1500lbs seed destroyed in Yuma, AZ
97-289-07n	97-314XRAB	Final report submitted 10/20/99 500lbs seed destroyed in Yuma, AZ
97-289-08n	97-315XRAB	Final report submitted 10/20/99 500lbs seed destroyed
97-273-08n	97-285XR	Final report submitted 10/20/99 disposition of seed will be obtained

1998

98-033-06n	98-040XR	Final report will be submitted
98-035-04n	98-042XR	Final report submitted All seed stored in Colorado final disposition to be obtained
98-075-12n	98-150XR	Trial not planted Final report to be faxed
98-075-25n	98-151XR	Final report prepared will fax
98-030-05n	98-035XR	Weld County site 281lbs seed shipped to Monsanto St. Louis destroyed, Pondera County, MT and North Central station incinerated.
98-035-02n	98-041XR	Ward County, ND; Weld County, CO; & Walla Walla County, WA were never planted. Pondera County, MT - all seed destroyed, spread over plot and sprayed with herbicide.
98-224-03n	98-313XR	Sedgwick County, KS 150 pounds seed returned to Monsanto in St. Louis County, MO - distributed to three states; CO, MT, WA - 23 pounds each - remaining seed at Monsanto in St. Louis County, MO. Seeds from Chase County, NE were burned.

1998 Wheat Field Test Report
USDA # 98-224-03n Monsanto # 98-313XR

(b) (6), (b) (7)(C)

August 30, 2000

Monsanto Company

Location

(b) (4)

County

Sedgwick
Chase

State

KS
NE

Chase County, NE

Planting Date: September 24, 1998

Harvest Date: July 13, 1999

Vector Constructs/Line Numbers Planted: PV-TXGT05, lines 25372, 25397

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)

Sedgwick County, KS

Planting Date: October 13, 1998

Harvest Date: June 29, 1999

Vector Constructs/Line Numbers Planted: : PV-TXGT05, lines 25372, 25397

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

MONSANTO

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December 8, 2000

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

USDA Number

Monsanto number

98-333-06n	98-040XR
98-035-04n	98-042XR
98-224-03n	98-313XR
98-229-11n	98-324XRAB
98-261-03n	98-382XRAB
98-261-04n	98-383XRAB
99-039-13n	99-053XRAB
99-039-14n	99-054XRAB
99-047-09n	99-011XR
99-047-11n	99-013XR
99-048-16n	99-094XRA
99-064-15n	99-148XR
99-064-18n	99-144XR
99-092-04n	99-240XRAB
99-092-05n	99-241XRAB
99-095-16n	99-254XRAB
99-105-03n	99-256XRAB
99-126-12n	99-410XRAB
99-130-03n	99-474XRAB

OR120018_BR_012190

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If you have any questions concerning these reports, please do not hesitate to
contact me at (b) (6), (b) (7)(C)

Sincerely, /

(b) (6), (b) (7)(C)

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

9/22/98 12:40 pm

Notification Tracking Sheet

Bp number: 98-261-03n

App number: 98-382XRAB
Received: 9/18/98
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 10/18/98
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 314-737-7085

- | | Initial | Date |
|--|-----------------|-----------------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apl</i>] | [9/22/98] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>lgs</i>]* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [<i>lgs</i>] | [9/24/98]* <i>fed etc</i> |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	CA	*	*WR *
Interstate	*Dest*	HI	*	*WR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Orig*	CA	*	*WR *
Interstate	*Orig*	HI	*	*WR *
Interstate	*Orig*	MO	*	*SCR *
Release	*	CA	*	1*WR *
Release	*	HI	*	1*WR *

- | | | |
|---|----------------|--------------------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apl</i>] | [9/22/98] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> denial/withdraw | [<i>lgs</i>] | [10/22/98]* <i>lgs</i> |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>lgs</i>] | [10/23/98] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
98-382XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

17-Sep-98

98-261-03n

1. USDA Reference Number

2. Applicant Reference Number 98-382XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy
St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 10/17/98 - 10/17/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

CONFIDENTIAL

Monsanto Reference ID
98-382XRAB

designation of transformed line: 24756, 26248

Constructs: PV-TXGT04

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)

(b) (4)

- CBI

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVa/I2 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
98-382XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)
(b) (4) CBI

CBI

* Gene: CTP2-CP4 -- (b) (4)

CBI

(b) (4)

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVbe2 -- (b) (4)
(b) (4) CBI

CBI

* Gene: CTP2-CP4 -- (b) (4)

CBI

(b) (4)

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
98-382XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed to each location.

Return up to 2,000 lbs of wheat seed from each location.

ORIGIN:

CA
MO

HI

DESTINATION:

CA
MO

HI

Ship From:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C)

HI

(b) (6), (b) (7)(C)

MO

(b) (4)

St. Louis County, MO, (b) (4) J.S.A.

Ship To:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C)

HI

(b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
98-382XRAB

MO

[REDACTED] (b) (4) St. Louis County, MO (b) (4) U.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA(1)

HI(1)

CA

* [REDACTED] (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C)

Release Location: [REDACTED] (b) (4) Imperial County,
CA up to 2 acres.

HI

* [REDACTED] (b) (4) HI. Contact: (b) (6), (b) (7)(C)
Release Location: [REDACTED] (b) (4) HI up to 2 acres.

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Monsanto Reference ID
98-382XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
17-Sep-98

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

98-382XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

17-Sep-98

98-261-03n

1. USDA Reference Number

2. Applicant Reference Number

98-382XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 10/17/98 - 10/17/99

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

Monsanto Reference ID
98-382XRAB

designation of transformed line: 24756, 26248

Constructs: PV-TXGT04

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-382XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbe2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-382XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed to each location.

Return up to 2,000 lbs of wheat seed from each location.

ORIGIN:

CA
MO

HI

DESTINATION:

CA
MO

HI

Ship From:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C), (b) (4)

HI

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C), (b) (4)

HI

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

Monsanto Reference ID
98-382XRAB

CA(1)

HI(1)

CA

*

(b) (4)

Yuma County, AZ. Contact

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Release Location:
CA up to 2 acres.

(b) (4)

Imperial County,

HI

(b) (6), (b) (7)(C), (b) (4)

HI. Contact

(b) (6), (b) (7)(C), (b) (4)

Release Location:

(b) (4)

HI up to 2 acres.

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Monsanto Reference ID
98-382XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

17-Sep-98

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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
98-382XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

17-Sep-98

98-261-03n

1. USDA Reference Number

2. Applicant Reference Number 98-382XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 10/17/98 - 10/17/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

Monsanto Reference ID
98-382XRAB

designation of transformed line: 24756, 26248

Constructs: PV-TXGT04

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-382XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbe2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-382XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed to each location.

Return up to 2,000 lbs of wheat seed from each location.

ORIGIN:

CA
MO

HI

DESTINATION:

CA
MO

HI

Ship From:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C), (b) (4)

HI

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4) J.S.A.

Ship To:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C), (b) (4)

HI

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4) J.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

Monsanto Reference ID
98-382XRAB

CA(1)

HI(1)

CA

(b) (4)

Yuma County, AZ. Contact

(b) (6), (b) (7)(C), (b) (4)

(b)

Release Location:
CA up to 2 acres.

(b) (4)

Imperial County,

HI

(b) (4)

HI. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location:

(b) (4)

HI up to 2 acres.

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CB I DELETED

Monsanto Reference ID
98-382XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (4)

Monsanto Company

17-Sep-98

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 22, 1998

Dear Ms. Hass:

Enclosed is notification 98-261-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-03n	Applicant #:	98-382XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012215

file copy

Mr. Larry Nakahara, Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

September 22, 1998

Dear Mr. Nakahara:

Enclosed is notification 98-261-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-03n	Applicant #:	98-382XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012216

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 22, 1998

Dear Mr. Brown:

Enclosed is notification 98-261-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-03n	Applicant #:	98-382XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012217

Confirmation Report-Memory Send

Time : 10-22-98 05:34pm
Tel line 1 : +3017348910
Tel line 2 : +
Name : USDA

Job number : 886
Date : 10-22 05:33pm
To : 913147377085
Document Pages : 02
Start time : 10-22 05:33pm
End time : 10-22 05:34pm
Pages sent : 02

Job number : 886

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

October 22, 1998

(b) (6), (b) (7)(C)

700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 22, 1998.

Interstate movement and Release
Notification no. 98-261-03n (98-352IRAB)
Regulated article - Wheat
Destinations - California, Hawaii, Missouri

This acknowledgment does not authorize use of "challenge organisms" for field test.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Mr. Dennis Tokunaka, Hawaii Department of Agriculture, Plant Quarantine Branch, 635 Mua Street, Kahului, (Maui) at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.
 - b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.



APHIS - Protecting America's Agriculture

An Equal Opportunity Employer

OR120018_BR_012218

1998 Wheat Field Test Report
USDA # 98-261-03n Monsanto # 98-382XRAB
(b) (6), (b) (7)(C)
August 31, 2000

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Yuma Honolulu	AZ HI

Yuma County, AZ

Planting Date: October 27, 1998

Harvest Date: May 10, 1999

Vector Constructs/Line Numbers Planted: PV-TXGT04, line 24756; PV-TXGT05 lines 25372, 25397, 25463

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)

Honolulu, HI

Planting Date: 1st planting November 19-23, 1998, 2nd planting December 17, 1998

Harvest Date: 1st March 1-5, 1999, 2nd March 29, 1999

Vector Constructs/Line Numbers Planted: PV-TXGT04 lines 24756, 26248, PV-TXGT05 lines 25372, 25397, 25463

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

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December 8, 2000

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

USDA Number

Monsanto number

98-333-06n

98-040XR

98-035-04n

98-042XR

98-224-03n

98-313XR

98-229-11n

98-324XRAB

98-261-03n

98-382XRAB

98-261-04n

98-383XRAB

99-039-13n

99-053XRAB

99-039-14n

99-054XRAB

99-047-09n

99-011XR

99-047-11n

99-013XR

99-048-16n

99-094XRA

99-064-15n

99-148XR

99-064-18n

99-144XR

99-092-04n

99-240XRAB

99-092-05n

99-241XRAB

99-095-16n

99-254XRAB

99-105-03n

99-256XRAB

99-126-12n

99-410XRAB

99-130-03n

99-474XRAB

OR120018_BR_012221

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If you have any questions concerning these reports, please do not hesitate to contact me at (b) (6), (b) (7)(C)

Sincerely, /

(b) (6), (b) (7)(C)

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

9/22/98 12:40 pm

Notification Tracking Sheet

Bp number: 98-261-04n

App number: 98-383XRAB
Received: 9/18/98
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 10/18/98
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 314-737-7085

Begin movement: 10/17/98
End movement: 10/17/99
Begin release: 10/17/98
End release: 10/17/99
Acre: 4.00
CBI status: CBI

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[aid]	[9/22/98]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[Shumler]*	[9/24/98]*
3. <input checked="" type="checkbox"/> Letter of notification to State	[lego]	[9/24/98]* fedex
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	CA	*	*WR	*	[]
Interstate	*Dest*	HI	*	*WR	*	[]
Interstate	*Dest*	MO	*	*SCR	*	[]
Interstate	*Orig*	CA	*	*WR	*	
Interstate	*Orig*	HI	*	*WR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Release	*	CA	*	1*WR	*	[]
Release	*	HI	*	1*WR	*	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[aid]	[9/24/98]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw	[lego]	[10/22/98]* fax
7. <input checked="" type="checkbox"/> Enter final data into database	[lego]	[10/30/98]

OR120018_BR_012223

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CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
98-383XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

17-Sep-98

98-261-04n

1. USDA Reference Number

2. Applicant Reference Number 98-383XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy
St. Louis, MO 63198

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release 10/17/98 - 10/17/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

CONFIDENTIAL

Monsanto Reference ID
98-383XRAB

designation of transformed line: 24756, 26248

Constructs: PV-TXGT04

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVa/I2 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
98-383XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVbe2 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
98-383XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 40 lbs. of wheat seed to each location.

Return up to 2,000 lbs. of wheat seed from each location.

ORIGIN:

CA
MO

HI

DESTINATION:

CA
MO

HI

Ship From:

CA

(b) (4)

Imperial County, CA

HI

(b) (4), (b) (6), (b) (7)(C)

HI ,

(b) (4), (b) (6), (b) (7)(C)

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

CA

(b) (4)

Imperial County, CA

HI

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

HI

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

Monsanto Reference ID
98-383XRAB

MO

(b) (4) St. Louis, St. Louis County, MO, (b) (4) U.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CA(1)

HI(1)

CA

* (b) (4) Yuma County, AZ. Contact: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Imperial County,
CA up to 2 acres.

HI

* (b) (4), (b) (6), (b) (7)(C) HI. Contact: (b) (4), (b) (6), (b) (7)(C)
Release Location: (b) (4) HI up to 2 acres.

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Monsanto Reference ID
98-383XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
17-Sep-98

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CB I DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

98-383XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

17-Sep-98

98-261-04n

1. USDA Reference Number

2. Applicant Reference Number 98-383XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 10/17/98 - 10/17/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

Monsanto Reference ID
98-383XRAB

designation of transformed line: 24756, 26248

Constructs: PV-TXGT04

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-383XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbe2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-383XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 40 lbs. of wheat seed to each location.

Return up to 2,000 lbs. of wheat seed from each location.

ORIGIN:

CA
MO

HI

DESTINATION:

CA
MO

HI

Ship From:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C), (b) (4)

Honolulu, HI

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C), (b) (4)

HI

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

Monsanto Reference ID
98-383XRAB

CA(1)

HI(1)

CA

* (b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Imperial County,
CA up to 2 acres.

HI

* (b) (6), (b) (7)(C), (b) (4) HI. Contact (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) HI up to 2 acres.

MONSANTO

Food • Health • Hope



CBI DELETED

Monsanto Reference ID
98-383XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

17-Sep-98

MONSANTO

Food • Health • Hope



CB I DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
98-383XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

17-Sep-98

98-261-04n

1. USDA Reference Number

2. Applicant Reference Number 98-383XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release 10/17/98 - 10/17/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

Monsanto Reference ID
98-383XRAB

designation of transformed line: 24756, 26248

Constructs: PV-TXGT04

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-383XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbe2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-383XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 40 lbs. of wheat seed to each location.

Return up to 2,000 lbs. of wheat seed from each location.

ORIGIN:

CA
MO

HI

DESTINATION:

CA
MO

HI

Ship From:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C), (b) (4)

HI

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

CA

(b) (4)

Imperial County, CA

HI

(b) (6), (b) (7)(C), (b) (4)

HI

(b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

Monsanto Reference ID
98-383XRAB

CA(1)

HI(1)

CA

^{*} (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Yuma County, AZ. Contact:

(b) (6), (b) (7)(C), (b) (4)

Release Location:
CA up to 2 acres.

(b) (4)

Imperial County,

HI

(b) (6), (b) (7)(C), (b) (4)

HI. Contact:

(b) (6), (b) (7)(C), (b) (4)

Release Location:

(b) (4)

HI up to 2 acres.

file copy

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 22, 1998

Dear Ms. Hass:

Enclosed is notification 98-261-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-04n	Applicant #:	98-383XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012246

file copy

Mr. Larry Nakahara, Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

September 22, 1998

Dear Mr. Nakahara:

Enclosed is notification 98-261-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-04n	Applicant #:	98-383XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012247

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 22, 1998

Dear Mr. Brown:

Enclosed is notification 98-261-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-04n	Applicant #:	98-383XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012248

Post-it® Fax Note	7671	Date	10/1	# of pages	2
To	MARY JACKSON	From	Kris PERLES		
Co./Dept		Co.			
Phone #		Phone #			
Fax #		Fax #			



United States
Department of
Agriculture

Animal &
Plant Health
Inspector

Ms. Barbara Hass, State Regulatory Official
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

September 22, 1998

Dear Ms. Hass:

Enclosed is notification 98-261-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-04n	Applicant #:	98-383XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbara J. Hass

Signature: (b) (6), (b) (7)(C)

Date: September 30, 1998

State: California

OR120018_BR_012249

10-1-98

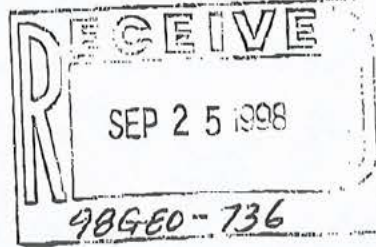


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Larry Nakahara, Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



September 22, 1998

Dear Mr. Nakahara:

Enclosed is notification 98-261-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-04n	Applicant #:	98-383XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada,
Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 28 October 1998

State: Hawaii



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

September 22, 1998

Dear Mr. Brown:

Enclosed is notification 98-261-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-261-04n	Applicant #:	98-383XRAB
Received:	September 18, 1998	Effective:	October 18, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

L. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 9-28-98

State: MO

October 29, 1998

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 29, 1998.

Interstate movement and Release
Notification no. 98-261-04n (98-383XRAB)
Regulated article - Wheat
Destinations - California, Hawaii, Missouri

This acknowledgment does not authorize use of "challenge organisms" for field test.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.
 - b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

OR120018_BR_012252

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
L. Nakahara, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Brownsville, TX
R. Stoaks, PPQ, WR, Sacramento, CA

File number 98-261-04n

Confirmation Report-Memory Send

Time : 10-29-98 05:02pm
Tel line 1 : +3017348910
Tel line 2 : +
Name : USDA

Job number : 021
Date : 10-29 05:00pm
To : 913147377085
Document Pages : 04
Start time : 10-29 05:01pm
End time : 10-29 05:02pm
Pages sent : 04
Job number : 021

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

October 29, 1998

(b) (6), (b) (7)(C)

700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 29, 1998.

Interstate movement and Release
Notification no. 98-261-04n (98-363KRAB)
Regulated article - Wheat
Destinations - California, Hawaii, Missouri

This acknowledgment does not authorize use of "challenge organisms" for field test.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.
 - b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.



APHIS - Planting Assistance Agreement

An Equal Opportunity Employer

OR120018_BR_012254

1998 Wheat Field Test Report
USDA # 98-261-04n Monsanto # 98-383XRAB

(b) (6), (b) (7)(C)
August 30, 2000

Monsanto Company

Location

Western Agricultural Center
Hawaii Research Center

County

Imperial
Honolulu

State

CA NOT PLANTED
HI

Honolulu County HI

Planting Date: November 23, 1998

Harvest Date: March 1-5, 1999

Vector Constructs/Line Numbers Planted: PV-TXGT04, line 24756, 26248. PV-TXGT05 line 25372, 25397, 25463

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

MONSANTO

Food • Health • Hope



December 8, 2000

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

USDA Number

Monsanto number

98-333-06n

98-040XR

98-035-04n

98-042XR

98-224-03n

98-313XR

98-229-11n

98-324XRAB

98-261-03n

98-382XRAB

98-261-04n

98-383XRAB

99-039-13n

99-053XRAB

99-039-14n

99-054XRAB

99-047-09n

99-011XR

99-047-11n

99-013XR

99-048-16n

99-094XRA

99-064-15n

99-148XR

99-064-18n

99-144XR

99-092-04n

99-240XRAB

99-092-05n

99-241XRAB

99-095-16n

99-254XRAB

99-105-03n

99-256XRAB

99-126-12n

99-410XRAB

99-130-03n

99-474XRAB

OR120018_BR_012256

MONSANTO

Food • Health • Hope



If you have any questions concerning these reports, please do not hesitate to
contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

10/14/98 1:15 pm

Notification Tracking Sheet

Bp number: 98-287-07n

App number: 98-425XRAB
Received: 10/14/98
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 11/13/98
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 11/12/98
End movement: 11/12/99
Begin release: 11/12/98
End release: 11/12/99
Acre: 2.00
CBI status: CBI
Fax: 314-737-7085

	Initial	Date
1. [✓] Assign Bp number and initial data entry	[ajd]	[10/14/98]
2. [✓] Review by biotechnologist	[Sherrill]*	[10/15/98]*
3. [✓] Letter of notification to State	[bgs]	[10/20/98]* fed-ek
4. [] State response		

	O/d	Loc	Site	Reg
Interstate *Dest*AZ *				*WR *
Interstate *Dest*MO *				*SCR *
Interstate *Orig*AZ *				*WR *
Interstate *Orig*MO *				*SCR *
Release * *AZ *				1*WR *

5. [✓] Enter genes into database	[ajd]	[10/15/98]
6. [✓] Letter of <u>acknowledgement</u> /denial/withdraw	[bgs]	[10/20/98]* fed-ek
7. [✓] Enter final data into database	[bgs]	[11/2/98]

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
98-425XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

13-Oct-98

98-287-07n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

98-425XRAB

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy
St. Louis, MO 63198

Phone
FAX
EMail

(b) (6), (b) (7)(C)

314-737-7085

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release 11/12/98 - 11/12/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype Glyphosate-tolerant

CONFIDENTIAL

Monsanto Reference ID
98-425XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVa/I2 -- (b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
98-425XRAB

designation of transformed line: 31849, TA-S339

Constructs: PV-TXGT11

genotype:

Gene of Interest

* Promoter: CMP3/I5 + leader 2 -- (b) (4)

(b) (4) CBI

* Gene: CTP2-CP4 -- (b) (4)

(b) (4) CBI

* Terminator: NOS 3' +2 - (b) (4)

(b) (4) CBI

Gene of Interest

* Promoter: CMoVa/I4 -- The 35S cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region.

* Gene: CTP2-CP4 -- (b) (4)

(b) (4) CBI

* Terminator: M1 3' -- (b) (4)

(b) (4) CBI

CONFIDENTIAL

Monsanto Reference ID
98-425XRAB

designation of transformed line: 33512, 35710, 35718, 35845, 35850, 36332

Constructs: PV-TXGT12

genotype:

Gene of Interest

* Promoter: MP4 --

(b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 --

(b) (4)

(b) (4)

CBI

* Terminator: M1 --

(b) (4)

(b) (4)

CBI

Gene of Interest

* Promoter: CMP 3/I5 --

(b) (4)

(b) (4)

CBI

* Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
98-425XRAB

designation of transformed line: TA-S342, TA-S343, TA-S529, TA-S530, TA-S537

Constructs: PV-TXGT13

genotype:

Gene of Interest

* Promoter: MP4 --

(b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 --

(b) (4)

(b) (4)

CBI

* Terminator: M1 3' --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID
98-425XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 40 lbs of wheat seed.

Return up to 1,000 lbs. of wheat seed after harvest.

ORIGIN:

AZ

MO

DESTINATION:

AZ

MO

Ship From:

AZ

(b) (4)

Yuma County, AZ

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

AZ

(b) (4)

Yuma County, AZ

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ(1)

AZ

CONFIDENTIAL

Monsanto Reference ID
98-425XRAB

* [REDACTED] (b) (4) Yuma County, AZ. Contact: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Release Location: [REDACTED] (b) (4) Yuma County, AZ up to 2 acres.

Comments: Section 1, Township 10S, Range 24W

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CONFIDENTIAL

Monsanto Reference ID
98-425XRAB

MONSANTO COMPANY
200 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
13-Oct-98

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CB I DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

98-425XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

13-Oct-98

98-287-07n

1. USDA Reference Number

2. Applicant Reference Number 98-425XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 11/12/98 - 11/12/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype Glyphosate-tolerant

Monsanto Reference ID
98-425XRAB

designation of transformed line: 33391, 33456, 33463

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-425XRAB

designation of transformed line: 31849, TA-S339

Constructs: PV-TXGT11

genotype:

Gene of Interest

- * Promoter: CMP3/I5 + leader 2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' +2 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMoVa/I4 -- The 35S cauliflower mosaic virus (CaMV) promoter with the duplicated enhancer region.
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID
98-425XRAB

designation of transformed line: 33512, 35710, 35718, 35845, 35850, 36332

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-425XRAB

designation of transformed line: TA-S342, TA-S343, TA-S529, TA-S530, TA-S537

Constructs: PV-TXGT13

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID
98-425XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 40 lbs of wheat seed.

Return up to 1,000 lbs. of wheat seed after harvest.

ORIGIN:

AZ

MO

DESTINATION:

AZ

MO

Ship From:

AZ

(b) (4)

Yuma County, AZ

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

AZ

(b) (4)

Yuma County, AZ

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ(1)

AZ

*

(b) (4)

Yuma County, AZ. Contact: (b) (4), (b) (6), (b) (7)(C)

(b) (7), (b) (7)(C), (b) (7)(D)

Release Location: (b) (4) Yuma County, AZ up to 2 acres.

Comments: \$ (b) (4)

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CBI DELETED

Monsanto Reference ID
98-425XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
13-Oct-98

file copy

Mr. Glen Thaxton, Asst. Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

October 14, 1998

Dear Mr. Thaxton:

Enclosed is notification 98-287-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-287-07n	Applicant #:	98-425XRAB
Received:	October 14, 1998	Effective:	November 13, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012278

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

October 14, 1998

Dear Mr. Brown:

Enclosed is notification 98-287-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-287-07n	Applicant #:	98-425XRAB
Received:	October 14, 1998	Effective:	November 13, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012279



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Glen Thaxton, Asst. Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

October 14, 1998

Dear Mr. Thaxton:

Enclosed is notification 98-287-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-287-07n	Applicant #:	98-425XRAB
Received:	October 14, 1998	Effective:	November 13, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 10/22/98

State: Arizona



10/27/98



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

October 14, 1998

Dear Mr. Brown:

Enclosed is notification 98-287-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 98-287-07n
Received: October 14, 1998
Institution: Monsanto
Interstate destination: AZ MO
Release destination: AZ

Applicant #: 98-425XRAB
Effective: November 13, 1998
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dyanne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 10-27-98

State: MO



10/27/98

October 30, 1998

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after November 13, 1998.

Interstate movement and release
Notification no. 98-287-07n (98-425XRAB)
Regulated article - Wheat
Destination(s) - Arizona, Missouri

This acknowledgment does not authorize use of "challenge organisms" for field test.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

G. Thaxton, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Brownsville, TX
R. Stoaks, PPQ, WR, Sacramento, CA
File number 98-287-07n

OR120018_BR_012282

FINAL REPORT

1998

Wheat

(b) (6), (b) (7)(C)

Monsanto Company

USDA Ref. # 98-287-07n

Monsanto Ref. # 98-425XRAB

Site Locations

(b) (4)

County & State

Yuma County, Az.

County/State

Planting Date: 11-19-98

Harvest/Destruct Date & Method: 5-13-1999

Vector Constructs/Line Numbers Planted: PV-TXGT10 lines 33391, 33456, 33463 PV-TXGT11 lines 31849, TA-S339 PV-TXGT12 lines 33512, 35710, 35718, 35845, 35850, 36332 PV-TXGT13 TA-S342, TAS343, TA-S529, TA-S530, TA-S537

Purpose/Objective:

Field Monitoring for Disease Susceptibility

Field Monitoring for Insect Susceptibility

Field Monitoring for Plant Growth Characteristics

Field Monitoring for Weediness Characteristics

Field Monitoring for Plant Stand

Monitoring for Volunteer Plants

OR120018_BR_012283

ad
11/28/99

This field trial was monitored, throughout the growing season for insect and disease susceptibility, and plant growth and weediness characteristics. This field trial does not pose a plant pest risk to the unmodified recipient organism from which it was derived.

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

November 14, 2002

Mr. Tony Roman
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Mr. Roman;

Field releases under the following USDA notifications have been completed and we are now submitting final reports as required. Please find reports for:

USDA #	Monsanto #
99-266-03n	99-727XRAB
01-017-02n	2001-65XRAB
98-287-07n	98-425XRAB

If you have any questions, please call (b) (6), (b) (7)(C)

Sincerely, /

(b) (6), (b) (7)(C)

OR120018_BR_012285

CONFIDENTIAL

Wheat Field Test Report
USDA #98-287-07n Monsanto #98-425XRAB

AMENDED
November 14, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
7652	Yuma	AZ

Yuma County/AZ (7652)

Planting Date: 11/19/1998

Harvest Date: 05/13/1999

Vector Constructs/Line Numbers Planted: (b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

Wheat Field Test Report
USDA #98-287-07n Monsanto #98-425XRAB

AMENDED
November 14, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
7652	Yuma	AZ

Yuma County/AZ (7652)

Planting Date: 11/19/1998

Harvest Date: 05/13/1999

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

10/14/98 1:15 pm

Notification Tracking Sheet

Bp number: 98-287-08n

App number: 98-426XRAB
Received: 10/14/98
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 11/13/98
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 11/12/98
End movement: 11/12/99
Begin release: 11/12/98
End release: 11/12/99
Acre: 2.00
CBI status: CBI
Fax: 314-737-7085

	Initial	Date
1. [✓] Assign Bp number and initial data entry	[ajd]	[10/14/98]
2. [✓] Review by biotechnologist	[Slomthin]*	[10/15/98]*
3. [✓] Letter of notification to State	[legs]	[10/20/98]*
4. [] State response		

O/d	Loc	Site	Reg
Interstate	*Dest*	AZ *	*WR *
Interstate	*Dest*	MO *	*SCR *
Interstate	*Orig*	AZ *	*WR *
Interstate	*Orig*	MO *	*SCR *
Release	*	AZ *	1*WR *

5. [✓] Enter genes into database	[ajd]	[10/15/98]
6. [✓] Letter of <u>acknowledgement</u> /denial/withdraw	[legs]	[10/29/98]*
7. [✓] Enter final data into database	[legs]	[10/30/98]

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CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
98-426XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

13-Oct-98

98-287-08n

1. USDA Reference Number

2. Applicant Reference Number 98-426XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy
St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 11/12/98 - 11/12/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

Glyphosate-tolerant

CONFIDENTIAL

Monsanto Reference ID
98-426XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/I5 --

(b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 --

(b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVhe2 --

(b) (4)

(b) (4)

CBI

* Gene: CTP2-CP4 --

(b) (4)

(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
98-426XRAB

7. Mode of Transformation

Particle Bombardment

8. Introduction

Interstate Movement and Release

Ship up to 40 lbs. of wheat seed.

Return up to 1,000 lbs. of wheat seed after harvest.

ORIGIN:

AZ

MO

DESTINATION:

AZ

MO

Ship From:

AZ

(b) (4)

Yuma County, AZ

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

AZ

(b) (4)

Yuma County, AZ

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ(1)

AZ

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CONFIDENTIAL

Monsanto Reference ID
98-426XRAB

MONSANTO COMPANY
500 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company
13-Oct-98

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
98-426XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

13-Oct-98

98-287-08n

1. USDA Reference Number

2. Applicant Reference Number 98-426XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

(b) (7)(C), (b) (6)

FAX

314-737-7085

Email

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 11/12/98 - 11/12/99

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype Glyphosate-tolerant

Monsanto Reference ID
98-426XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbe2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
98-426XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 40 lbs. of wheat seed.

Return up to 1,000 lbs. of wheat seed after harvest.

ORIGIN:

AZ

MO

DESTINATION:

AZ

MO

Ship From:

AZ

(b) (4)

Yuma County, AZ

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

AZ

(b) (4)

Yuma County, AZ

MO

(b) (4)

St. Louis County, MO (b) (4) U.S.A.

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ(1)

AZ

*

(b) (4)

Yuma County, AZ. Contact:

(b) (7)(C), (b) (6), (b) (4)

(b) (7)(C), (b) (6), (b) (4)

Release Location:

(b) (4)

Yuma County, AZ up to 2 acres.

Comments:

(b) (4)

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Monsanto Reference ID
98-426XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

13-Oct-98

file copy

Mr. Glen Thaxton, Asst. Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

October 14, 1998

Dear Mr. Thaxton:

Enclosed is notification 98-287-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-287-08n	Applicant #:	98-426XRAB
Received:	October 14, 1998	Effective:	November 13, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012304

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

October 14, 1998

Dear Mr. Brown:

Enclosed is notification 98-287-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-287-08n	Applicant #:	98-426XRAB
Received:	October 14, 1998	Effective:	November 13, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012305



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Glen Thaxton, Asst. Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

October 14, 1998

Dear Mr. Thaxton:

Enclosed is notification 98-287-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 98-287-08n
Received: October 14, 1998
Institution: Monsanto
Interstate destination: AZ MO
Release destination: AZ

Applicant #: 98-426XRAB
Effective: November 13, 1998
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: John Paranjata

Signature: (b) (6), (b) (7)(C)

Date: 10/27/98

State: Arizona





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

October 14, 1998

Dear Mr. Brown:

Enclosed is notification 98-287-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	98-287-08n	Applicant #:	98-426XRAB
Received:	October 14, 1998	Effective:	November 13, 1998
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 10-27-98

State: MO



10/27/98

October 29, 1998

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after November 13, 1998.

Interstate movement and release
Notification no. 98-287-08n (98-426XRAB)
Regulated article - Wheat
Destination(s) - Arizona, Missouri

This acknowledgment does not authorize use of "challenge organisms" for field test.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

G. Thaxton, Arizona Dept. of Agric., Phoenix, AZ
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Brownsville, TX
R. Stoaks, PPQ, WR, Sacramento, CA
File number 98-287-08n

OR120018_BR_012308

FINAL REPORT
1998
Wheat

(b) (6), (b) (7)(C)
Monsanto Company

USDA Ref. # 98-287-08n

Monsanto Ref. # 98-426XRAB

Site Locations

(b) (4)

County & State

Yuma County, Az.

County/State

Planting Date: 11-19-98

Harvest/Destruct Date & Method: 6-15-1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose/Objective:

Field Monitoring for Disease Susceptibility

Field Monitoring for Insect Susceptibility

Field Monitoring for Plant Growth Characteristics

Field Monitoring for Weediness Characteristics

Field Monitoring for Plant Stand

Monitoring for Volunteer Plants

This field trial was monitored, throughout the growing season for insect and disease susceptibility, and plant growth and weediness characteristics. This field trial does not pose a plant pest risk to the unmodified recipient organism from which it was derived.

OR120018_BR_012309

ajd
11/22/99

CONFIDENTIAL

1998 Wheat Field Test Report
USDA #98-287-08N Monsanto #98-426XRAB

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
7652	Yuma	AZ

Yuma County/AZ (7652)

Planting Date: 11/19/1998

Harvest Date: 05/12/1999

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Disposition of the Harvested Material:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

(b) (4)

Additional Comments:

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

1999 Wheat Field Test Report
USDA #98-287-08N Monsanto #98-426XRAB

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
7652	Yuma	AZ

Yuma County/AZ (7652)

Planting Date: 11/19/1998

Harvest Date: 05/12/1999

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

2/10/99 10:44 am

Notification Tracking Sheet

Bp number: 99-039-15n

App number: 99-055XRAB
Received: 2/08/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/10/99
Phenotype: HT - Glyphosate tolerant
Comments:

Begin movement: 3/07/99
End movement: 3/06/00
Begin release: 3/07/99
End release: 3/06/00
Acre: 32.00
CBI status: CBI

Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Fax: 314-737-7085

- | | Initial | Date |
|--|----------|--------------------|
| 1. [✓] Assign Bp number and initial data entry | [ajb] | [2/10/99] |
| 2. [] Review by biotechnologist | [xzt]* | [2/10/99]* |
| 3. [✓] Letter of notification to State | [bgs] | [2/12/99]* Red X |
| 4. [] State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*CO	*	*WR *
Interstate	*Dest*ID	*	*WR *
Interstate	*Dest*MT	*	*WR *
Interstate	*Dest*ND	*	*SCR *
Interstate	*Dest*SD	*	*SCR *
Interstate	*Dest*WA	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*ND	*	*SCR *
Release	* *CO	*	1*WR *
Release	* *ID	*	1*WR *
Release	* *MT	*	1*WR *
Release	* *ND	*	2*SCR *
Release	* *SD	*	1*SCR *
Release	* *WA	*	2*WR *

- | | | |
|--|---------|-------------|
| 5. [✓] Enter genes into database | [ajb] | [2/10/99] |
| 6. [✓] Letter of acknowledgement/denial/withdraw | [bgs] | [3/1/99]* |
| 7. [✓] Enter final data into database | [bgs] | [3/2/99] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

St. Louis, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-055XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

05-Feb-99

99-039-15n

1. USDA Reference Number

2. Applicant Reference Number

99-055XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company

700 Chesterfield Village Pkwy

St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release

3/7/99 - 3/6/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

Glyphosate Tolerant

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Monsanto Reference ID
99-055XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)
(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)
(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVbe2 -- (b) (4)
(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)
(b) (4)

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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Monsanto Reference ID
99-055XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:
MO

ND

DESTINATION:

CO

ID

MT

ND

Not

SD

WA

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) S.A

ND

(b) (4), (b) (6), (b) (7)(C)

Cass County, ND (b) (4), (b) (6), (b) (7)(C)

Ship To:

CO

* (b) (4), (b) (6), (b) (7)(C)

Weld County, CO,

ID

* (b) (4), (b) (6), (b) (7)(C)

Ada County, ID,

(b) (4), (b) (6), (b) (7)(C)

MT

(b) (4), (b) (6), (b) (7)(C)

Cascade County, MT,

(b) (4), (b) (6), (b) (7)(C)

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Monsanto Reference ID
99-055XRAB

ND

(b) (4), (b) (6), (b) (7)(C) Cass County, ND, (b) (4), (b) (6), (b) (7)(C)

North Dakota

* (b) (4), (b) (6), (b) (7)(C) Ward County, North Dakota U.S.A., (b) (4), (b) (6), (b) (7)(C)

SD

(b) (4), (b) (6), (b) (7)(C) Roberts County, SD, (b) (4), (b) (6), (b) (7)(C)

WA

* (b) (4), (b) (6), (b) (7)(C) Walla Walla County, WA,
(b) (4), (b) (6), (b) (7)(C)

* (b) (4), (b) (6), (b) (7)(C) Adams County, WA (b) (4), (b) (6), (b) (7)(C)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CO(1)	ID(1)	MT(1)	ND(1)
North Dakota(1)	SD(1)	WA(2)	

CO

* (b) (4), (b) (6), (b) (7)(C) Weld County, CO. Contact: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Weld County, CO Up to 4 acres.

ID

* (b) (4), (b) (6), (b) (7)(C) Ada County, ID. Contact: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Release Location: Canyon County, ID Up to 4 acres.

MT

* (b) (4), (b) (6), (b) (7)(C) Cascade County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Release Location: Pondera County, MT Up to 4 acres.

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Monsanto Reference ID
99-055XRAB

ND

* (b) (4), (b) (6), (b) (7)(C) Cass County, ND, (b) (4), (b) (6), (b) (7)(C)

Release Location: Cass County, ND Up to 4 acres.

North Dakota

* (b) (4), (b) (6), (b) (7)(C), Ward County, North Dakota. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Ward County, North Dakota Up to 4 acres.

SD

* (b) (4), (b) (6), (b) (7)(C) Cass County, ND, (b) (4), (b) (6), (b) (7)(C)

Release Location: Roberts County, SD Up to 4 acres.

Comments: (b) (4) Roberts County, SD

WA

* (b) (4), (b) (6), (b) (7)(C) Walla Walla County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Walla Walla County, WA Up to 4 acres.

* (b) (4), (b) (6), (b) (7)(C) Whitman County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C) Whitman County, WA Up to 4 acres.

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Monsanto Reference ID
99-055XRAB

MONSANTO COMPANY
7000 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
05-Feb-99

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

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Monsanto Reference ID
99-055XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

05-Feb-99

99-039-15n

1. USDA Reference Number

2. Applicant Reference Number 99-055XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

E-Mail

(b) (6), (b) (7)(C)

@monsanto.com

4. Duration of Introduction

Interstate Movement and Release 3/7/99 - 3/6/2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype Glyphosate Tolerant

Monsanto Reference ID
99-055XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbe2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-055XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:	DESTINATION:
MO	CO
ND	MT
	Ne
	WA
	ID
	ND
	SD

Ship From:

MO

(b) (4) St. Louis County, MO, (b) (4) J.S.A

ND

* (b) (6), (b) (7)(C), (b) (4) Cass County, ND (b) (6), (b) (7)(C), (b) (4)

Ship To:

CO

* (b) (6), (b) (7)(C), (b) (4) Weld County, CO,
(b) (6), (b) (7)(C), (b) (4)

ID

* (b) (6), (b) (7)(C), (b) (4) Ada County, ID, (b) (6), (b) (7)(C), (b) (4)

MT

* (b) (6), (b) (7)(C), (b) (4) Cascade County, MT, (b) (6), (b) (7)(C), (b) (4)

ND

(b) (6), (b) (7)(C), (b) (4) Cass County, ND (b) (6), (b) (7)(C), (b) (4)

North Dakota

* (b) (6), (b) (7)(C), (b) (4) Ward County, North Dakota U.S.A., (b) (6), (b) (7)(C), (b) (4)

Monsanto Reference ID
99-055XRAB

SD

(b) (6), (b) (7)(C), (b) (4)

Roberts County, SD, (b) (6), (b) (7)(C), (b) (4)

WA

*

(b) (6), (b) (7)(C), (b) (4) Walla Walla County, WA,
(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Adams County, WA, (b) (6), (b) (7)(C), (b) (4)

Release Sites:**NUMBER OF STATES/TERRITORIES AND SITES:****CO(1)**

North

Dakota(1)

ID(1)

SD(1)

MT(1)

WA(2)

ND(1)**CO**

*

(b) (6), (b) (7)(C), (b) (4) Weld County, CO. Contact: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Weld County, CO Up to 4 acres.

ID

*

(b) (6), (b) (7)(C), (b) (4) Ada County, ID. Contact: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Release Location: Canyon County, ID Up to 4 acres.

MT

*

(b) (6), (b) (7)(C), (b) (4) Cascade County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Release Location: Pondera County, MT Up to 4 acres.

ND

*

(b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

Release Location: Cass County, ND Up to 4 acres.

North Dakota

*

(b) (6), (b) (7)(C), (b) (4) Ward County, North Dakota. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Ward County, North Dakota Up to 4 acres.

Monsanto Reference ID
99-055XRAB

SD

(b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

Release Location: Roberts County, SD Up to 4 acres.

Comments: On day of planting, seed will move to Roberts County, SD

WA

* (b) (6), (b) (7)(C), (b) (4) Walla Walla County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Walla Walla County, WA Up to 4 acres.

* (b) (6), (b) (7)(C), (b) (4) Whitman County, WA. Contact (b) (6), (b) (7)(C), (b) (4)

Release Location (b) (6), (b) (7)(C), (b) (4) Whitman County, WA Up to 4 acres.

MONSANTO

Food · Health · Hope



CBI DELETED

Monsanto Reference ID
99-055XRAB

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

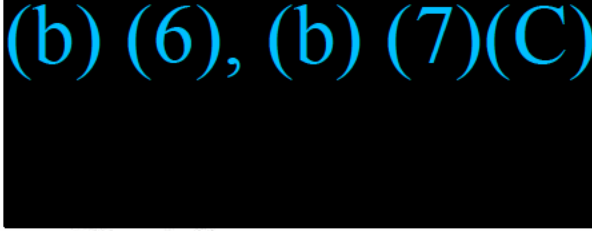
PHONE (314) 694-1000

• <http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

05-Feb-99

MONSANTO

Food • Health • Hope



CBI DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-055XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

05-Feb-99

99-039-15n

1. USDA Reference Number

2. Applicant Reference Number 99-055XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)

@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 3/7/99 - 3/6/2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype Glyphosate Tolerant

Monsanto Reference ID
99-055XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbe2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-055XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:
MO

ND

DESTINATION:

CO
MT
Noi
WA

ID
ND
SD

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A

ND

* (b) (6), (b) (7)(C), (b) (4)

Cass County, ND

(b) (6), (b) (7)(C), (b) (4), (b) (6), (b) (7)(C), (b) (4)

Ship To:

CO

(b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

Weld County, CO,

ID

(b) (6), (b) (7)(C), (b) (4)

Ada County, ID, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

Cascade County, MT, (b) (6), (b) (7)(C), (b) (4)

ND

* (b) (6), (b) (7)(C), (b) (4)

Cass County, ND,

(b) (6), (b) (7)(C), (b) (4)

North Dakota

* (b) (6), (b) (7)(C), (b) (4)

Ward County, North Dakota U.S.A.

(b) (6), (b) (7)(C), (b) (4)

Monsanto Reference ID
99-055XRAB

SD

(b) (6), (b) (7)(C), (b) (4) Roberts County, SD (b) (6), (b) (7)(C), (b) (4)

WA

(b) (6), (b) (7)(C), (b) (4) Walla Walla County, WA,

(b) (6), (b) (7)(C), (b) (4) Adams County, WA, (b) (6), (b) (7)(C), (b) (4)

Release Sites:**NUMBER OF STATES/TERRITORIES AND SITES:**

CO(1)	ID(1)	MT(1)	ND(1)
North	SD(1)	WA(2)	
Dakota(1)			

CO

(b) (6), (b) (7)(C), (b) (4) Weld County, CO. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Weld County, CO Up to 4 acres.

ID

* (b) (6), (b) (7)(C), (b) (4) Ada County, ID. Contact (b) (6), (b) (7)(C), (b) (4)

Release Location: Canyon County, ID Up to 4 acres.

MT

(b) (6), (b) (7)(C), (b) (4) Cascade County, MT. Contact (b) (6), (b) (7)(C), (b) (4)

Release Location: Pondera County, MT Up to 4 acres.

ND

* (b) (6), (b) (7)(C), (b) (4) Cass County, ND (b) (6), (b) (7)(C), (b) (4)

Release Location: Cass County, ND Up to 4 acres.

North Dakota

(b) (6), (b) (7)(C), (b) (4) Ward County, North Dakota. Contact (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Ward County, North Dakota Up to 4 acres.

Monsanto Reference ID
99-055XRAB

SD

* (b) (6), (b) (7)(C), (b) (4) Fargo, Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

Release Location: Roberts County, SD Up to 4 acres.

Comments: On day of planting, seed will move to Roberts County, SD

WA

(b) (6), (b) (7)(C), (b) (4) Walla Walla County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Walla Walla County, WA Up to 4 acres.

(b) (6), (b) (7)(C), (b) (4) Whitman County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4), (b) (6), (b) (7)(C) Whitman County, WA Up to 4 acres.

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 10, 1999

Dear Mr. Yergert:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012337

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 10, 1999

Dear Dr. Vega:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012338

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 10, 1999

Dear Dr. Gingery:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012339

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 10, 1999

Dear Mr. Nelson:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-15n Applicant #: 99-055XRAB
Received: February 8, 1999 Effective: March 10, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: CO ID MT ND SD WA
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012340

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 10, 1999

Dear Mr. Fridley:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012341

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 1999

Dear Mr. Wessels:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012342



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

6661 9-1 831
FEB 16 1999

RECEIVED
FEB 16 1999

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 10, 1999

Dear Mr. Yergert:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Yergert

Signature: (b) (6), (b) (7)(C)

Date: February 17, 1999

State: Colorado



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_012343

2-17-99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

FEB 16 1999

PLANT INDUSTRIES

February 10, 1999

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

Dear Dr. Vega:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature (b) (6), (b) (7)(C) _____

Date: Feb. 16, 1999

State: IDAHO

OR120018_BR 012344



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Handwritten signature/initials

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 10, 1999

Dear Dr. Gingery:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: **(b) (6), (b) (7)(C)**

Date: February 25, 1999

State: Montana





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 10, 1999

Dear Mr. Nelson:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-15n Applicant #: 99-055XRAB
Received: February 8, 1999 Effective: March 10, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: CO ID MT ND SD WA
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID R. NELSON

Signature

(b) (6), (b) (7)(C)

Date: 2-15-99

State: ND



APHIS - Protecting American Agriculture

OR120018_BR_012346

As Issued to Regulatory Employees

2-16-99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 10, 1999

Dear Mr. Fridley:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-15n Applicant #: 99-055XRAB
Received: February 8, 1999 Effective: March 10, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: CO ID MT ND SD WA
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/22/99

State: Kevin Fridley





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 10, 1999

Dear Mr. Wessels:

Enclosed is notification 99-039-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-15n	Applicant #:	99-055XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/17/99

State: WA



2/17/99

March 1, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after March 10, 1999.

Interstate movement

Notification no. 99-039-15n (99-055XRAB)

Regulated article - Wheat

Destinations - Colorado, Idaho, Montana, North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Yerger, Colorado Dept. of Agric., Lakewood, CO
R. Vega, Idaho Dept. of Agric., Boise, ID
G. Gingery, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Brownsville, TX
File number 99-039-15n

OR120018_BR_012349

1999 Wheat Field Trial Report
USDA # 99-039-15n Monsanto # 99-055XRAB

(b) (6), (b) (7)(C)

December 12, 2000
Monsanto Company

Location	County	State
(b) (4)	Weld	CO
(b) (6), (b) (7)(C), (b) (4)	Canyon	ID
(b) (4)	Pondera	MT
(b) (4)	Ward	ND
(b) (6), (b) (7)(C), (b) (4)	Cass	ND
(b) (4)	Roberts	SD (Not Planted)
(b) (4)	Whitman	WA
(b) (4)	Walla Walla	WA

Canyon County, ID

This information will be provided at a later date.

Weld County, CO

Planting Date: March 29, 1999

Destruct/Harvest Date: July 23 and July 26, 1999

Vector Constructs/Line Numbers Planted (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)
(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)
(b) (4)

Monitoring for Volunteer Plants: (b) (4)

(b) (4)

Pondera County, MT

Planting Date: April 20, 1999

Destruct/Harvest Date: August 24, 2000

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of trial: RR wheat live study

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

(b) (4)

Ward County, ND

Planting Date: May 26, 1999

Destruct/ Harvest Date: September 29, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants

(b) (4)

(b) (4)

Whitman County, WA

Planting Date: April 16, 1999

Destruct/Harvest Date September 3, 1999

Vector Constructs/Line Numbers Planted (b) (4)

Purpose of trial; (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics (b) (4)

(b) (4)

Monitoring for Volunteer Plants: (b) (4)

(b) (4)

Walla Walla, Wa

Planting Date: April 14, 1999

Destruct/Harvest Date: August 16, 1999

Vector Constructs/Line Numbers Planted (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)

2/17/99 5:50 pm

Notification Tracking Sheet

Bp number: 99-048-16n

App number: 99-094XRA
Received: 2/17/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/19/99
Phenotype: HT - Glyphosate tolerant

Begin movement: 3/16/99
End movement: 3/15/00
Begin release: 3/16/99
End release: 3/15/00
Acre: 14.00
CBI status: CBI

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway North

Address3:

Address4:

City/State/Zip: St. Louis, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax:

314-737-7085

- | | Initial | Date |
|--|----------|------------------|
| 1. [] Assign Bp number and initial data entry | [JEL] | [2/17/99] |
| 2. [] Review by biotechnologist | [JEL]* | []* |
| 3. [✓] Letter of notification to State | [BGS] | [2/22/99]* fax |
| 4. [] State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*ID	*	*WR	*
Interstate	*Dest*MT	*	*WR	*
Interstate	*Dest*ND	*	*SCR	*
Interstate	*Dest*WA	*	*WR	*
Interstate	*Orig*MO	*	*SCR	*
Release	*ID	*	1*WR	*
Release	*MT	*	2*WR	*
Release	*ND	*	3*SCR	*
Release	*OR	*	1*WR	*

- | | | |
|--|---------|------------------|
| 5. [✓] Enter genes into database | [JEL] | [2/18/99] |
| 6. [✓] Letter of acknowledgement/denial/withdraw | [BGS] | [3/18/99]* fax |
| 7. [✓] Enter final data into database | [BGS] | [3/22/99] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

St. Louis, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-094XRA

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

14-Feb-99

99-048-16n

1. USDA Reference Number

2. Applicant Reference Number 99-094XRA

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy
St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release 3/16/99 - 3/15/2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype Glyphosate tolerant

CONFIDENTIAL

Monsanto Reference ID
99-094XRA

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMP3/IS -- (b) (4)
(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

CBI

(b) (4)

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMoVhe2 -- (b) (4)
(b) (4)

CBI

* Gene: CTP2-CP4 -- (b) (4)

CBI

(b) (4)

* Terminator: E9 3' -- A 3' non-translated region of the pea *rbcS*-E9 gene.

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Monsanto Reference ID
99-094XRA

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 250 lbs. of wheat seed.

ORIGIN:
MO

DESTINATION:
ID
ND

MT
WA

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) J.S.A.

Ship To:

ID

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Ada County, ID, (b) (4)

MT

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Cascade County, MT, (b) (4) (b) (4), (b) (6), (b) (7)(C)

ND

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Burke County, ND, (b) (4) (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Cass County, ND, (b) (4), (b) (6), (b) (7)(C)

WA

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Walla

Walla County, WA, (b) (4) (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4)

Adams County, WA, (b) (4)

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Monsanto Reference ID
99-094XRA

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(1)
WA(2)

MT(2)

ND(3)

OR(1)

ID

* (b) (4) Ada County, ID. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C) Bingham County, ID up to 1 acres.

MT

* (b) (4) Cascade County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C) Rondera County, MT up to 2 acres.

* (b) (4) Cascade County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C) Teton County, MT up to 1 acres.

ND

* (b) (4) Burke County, ND. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C) Mountrail County, ND up to 1 acres.

* (b) (4) Burke County, ND. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C) Burke County, ND up to 2 acres.

* (b) (4), (b) (6), (b) (7)(C) Cass County, ND (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C) Cass County, ND up to 2 acres.

OR

* (b) (4) Adams County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Sherman County, OR up to 2 acres.

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Monsanto Reference ID
99-094XRA

WA

* [REDACTED] (b) (4) Walla Walla County, WA.
Contact (b) (4), (b) (6), (b) (7)(C) [REDACTED]

Release Location: (b) (4) Walla Walla County,
WA up to 3 acres.

* [REDACTED] (b) (4) Adams County, WA. Contact (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C) Whitman County, WA up to 2 acres.

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Monsanto Reference ID
99-094XRA

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

14-Feb-99

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-094XRA

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

14-Feb-99

99-048-16n

1. USDA Reference Number

2. Applicant Reference Number 99-094XRA

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 314-737-7085

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

EEmail (b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release 3/16/99 - 3/15/2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype Glyphosate tolerant

Monsanto Reference ID
99-094XRA

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05
genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbc2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: E9 3' -- A 3' non-translated region of the pea *rbcS*-E9 gene.

Monsanto Reference ID
99-094XRA

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 250 lbs. of wheat seed.

ORIGIN:
MO

DESTINATION:
ID
ND

MT
WA

Ship From:

MO

Monsanto Company, 700 Chesterfield Parkway No., St. Louis, St. Louis County, MO, 63198 U.S.A.

Ship To:

ID

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Ada County, ID, (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Cascade County, MT, (b) (4) (b) (6), (b) (7)(C), (b) (4)

ND

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Burke County, ND, (b) (4) (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

WA

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Walla County, WA, (b) (4) (b) (6), (b) (7)(C), (b) (4)

Walla

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Adams County, WA, (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(1)

MT(2)

ND(3)

OR(1)

Monsanto Reference ID
99-094XRA

WA(2)

ID

* (b) (4) Ada County, ID. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Bingham County, ID up to 1 acres.

MT

* (b) (4) MT. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4), (b) (6), (b) (7)(C) Pondera County, MT up to 2 acres.

* (b) (4) Cascade County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Teton County, MT up to 1 acres.

ND

* (b) (4) Burke County, ND. Contact: (b) (4), (b) (6), (b) (7)(C), (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Mountrail County, ND up to 1 acres.

* (b) (4) Burke County, ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Burke County, ND up to 2 acres.

* (b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Cass County, ND up to 2 acres.

OR

* (b) (4) Adams County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Sherman County, OR up to 2 acres.

WA

* (b) (4) Walla Walla County, WA.
Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: PNW Center, Walla Walla Regional Airport, Walla Walla County, WA up to 3 acres.

* (b) (4) Adams County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Whitman County, WA up to 2 acres.

MONSANTO

Food • Health • Hope



CBI DELETED

Monsanto Reference ID
99-094XRA

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
14-Feb-99

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700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-094XRA

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

14-Feb-99

99-048-16n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

99-094XRA

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release 3/16/99 - 3/15/2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype Glyphosate tolerant

Monsanto Reference ID
99-094XRA

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVbe2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: E9 3' -- A 3' non-translated region of the pea *rbcS-E9* gene.

Monsanto Reference ID
99-094XRA

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 250 lbs. of wheat seed.

ORIGIN:

MO

DESTINATION:

ID

MT

ND

WA

Ship From:

MO

(b) (4)

St. Louis County, MO, (b) (4) U.S.A.

Ship To:

ID

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Ada County, ID, (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Cascade County, MT, (b) (4) (b) (6), (b) (7)(C), (b) (4)

ND

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Burke County, ND, (b) (4) (b) (6), (b) (7)(C), (b) (4)

* (b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

WA

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Walla

Walla County, WA, (b) (4) (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (4)

Adams County, WA, (b) (4)

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ID(1)

MT(2)

ND(3)

OR(1)

Monsanto Reference ID
99-094XRA

WA(2)

ID

* (b) (6), (b) (7)(C), (b) (4) Ada County, ID. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Bingham County, ID up to 1 acres.

MT

* (b) (6), (b) (7)(C), (b) (4) Cascade County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Pondera County, MT up to 2 acres.

* (b) (6), (b) (7)(C), (b) (4) Cascade County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Teton County, MT up to 1 acres.

ND

* (b) (6), (b) (7)(C), (b) (4) Burke County, ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Mountrail County, ND up to 1 acres.

* (b) (6), (b) (7)(C), (b) (4) Burke County, ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4), (b) (6), (b) (7)(C) Burke County, ND up to 2 acres.

* (b) (6), (b) (7)(C), (b) (4) (b) (6), (b) (7)(C), (b) (4) Cass County, ND (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Cass County, ND up to 2 acres.

OR

* (b) (6), (b) (7)(C), (b) (4) (b) (4) Adams County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Sherman County, OR up to 2 acres.

WA

* (b) (6), (b) (7)(C), (b) (4) (b) (4) Walla Walla County, WA.
Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Walla Walla County, WA up to 3 acres.

* (b) (6), (b) (7)(C), (b) (4) (b) (4) Adams County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Whitman County, WA up to 2 acres.

MONSANTO

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CBI DELETED

Monsanto Reference ID
99-094XRA

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

14-Feb-99

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 17, 1999

Dear Dr. Vega:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-048-16n	Applicant #:	99-094XRA
Received:	February 17, 1999	Effective:	March 19, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MT ND WA		
Release destination:	ID MT ND OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012420

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 17, 1999

Dear Dr. Gingery:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-048-16n	Applicant #:	99-094XRA
Received:	February 17, 1999	Effective:	March 19, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MT ND WA		
Release destination:	ID MT ND OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012421

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 17, 1999

Dear Mr. Nelson:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-048-16n	Applicant #:	99-094XRA
Received:	February 17, 1999	Effective:	March 19, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MT ND WA		
Release destination:	ID MT ND OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012422

file copy

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

February 17, 1999

Dear Mr. Griesbach:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-048-16n	Applicant #:	99-094XRA
Received:	February 17, 1999	Effective:	March 19, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MT ND WA		
Release destination:	ID MT ND OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012423

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 17, 1999

Dear Mr. Wessels:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-048-16n	Applicant #:	99-094XRA
Received:	February 17, 1999	Effective:	March 19, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MT ND WA		
Release destination:	ID MT ND OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012424



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

FEB 23 1999

PLANT INDUSTRIES

February 17, 1999

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

Dear Dr. Vega:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number: 99-048-16n Applicant: 99-094XRA
Received: February 17, 1999 Effective: March 19, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MT ND WA
Release destination: ID MT ND OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

(b) (6), (b) (7)(C)

Date: Feb. 23, 1999

State: IDAHO



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2/23/99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Pawcatuck, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 17, 1999

Dear Dr. Gingery:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ap. number: 99-048-16n Applicant #: 99-094XRA
Received: February 17, 1999 Effective: March 19, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MT ND WA
Release destination: ID MT ND OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION



State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: February 25, 1999

State: Montana



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2-25-99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Pawcatuck, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 17, 1999

Dear Mr. Nelson:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-048-16n	Applicant #:	99-094XRA
Received:	February 17, 1999	Effective:	March 19, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MT ND WA		
Release destination:	ID MT ND OR		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID R NELSON

Signature: (b) (6), (b) (7)(C)

Date: 2-23-99

State: ND



APHIS - Plant Health Inspection Service

OR120018_BR_012427

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

2-23-99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

February 17, 1999

Dear Mr. Griesbach:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-048-16n Applicant #: 99-094XRA
Received: February 17, 1999 Effective: March 19, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MT ND WA
Release destination: ID MT ND OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Daniel J. Hilburn

Signature: (b) (6), (b) (7)(C)

Date: March 9, 1999

State: Oregon



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OR120018_BR_012428



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Beltsville, MD 20717

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 17, 1999

Dear Mr. Wessels:

Enclosed is notification 99-048-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number: 99-048-16n Applicant: 99-094XRA
Received: February 17, 1999 Effective: March 19, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MT ND WA
Release destination: ID MT ND OR

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilia (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hattmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: WA 2/23/99

State: WA



APHIS - Protecting American Agriculture

OR120018_BR_012429

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2/23/99

March 18, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after March 19, 1999.

Interstate movement and release

Notification no. 99-048-16n (99-094-XRA)

Regulated article - Wheat

Destination(s) - Idaho, Montana, North Dakota, Oregon, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
G. Gingery, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
J. Griesbach, Oregon Dept. of Agric., Salem, OR
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Brownsville, TX
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-048-16n

OR120018_BR_012430

Confirmation Report-Memory Send

Time : 03-22-99 11:54am
Tel line 1 : +3017348910
Tel line 2 : +
Name : USDA

Job number : 466
Date : 03-22 11:53am
To : 913147377085
Document Pages : 01
Start time : 03-22 11:53am
End time : 03-22 11:54am
Pages sent : 01
Job number : 466

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

6700 River Road
Riverdale MD 20737

March 18, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear

(b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after March 19, 1999.

Interstate movement and release
Notification no. 99-048-15a (99-094-3RA)

Regulated article - Wheat

Destination(s) - Idaho, Montana, North Dakota, Oregon, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Ratmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
G. Gingery, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
J. Griesbach, Oregon Dept. of Agric., Salem, OR
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWesse, PPQ, SCR, Brownsville, TX
R. Steaks, PPQ, WR, Sacramento, CA



OFFICE OF PLANT PROTECTION AND QUARANTINE

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

OR120018_BR_012431

MONSANTO

Food • Health • Hope



December 8, 2000

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

<u>USDA Number</u>	<u>Monsanto number</u>
98-333-06n	98-040XR
98-035-04n	98-042XR
98-224-03n	98-313XR
98-229-11n	98-324XRAB
98-261-03n	98-382XRAB
98-261-04n	98-383XRAB
99-039-13n	99-053XRAB
99-039-14n	99-054XRAB
99-047-09n	99-011XR
99-047-11n	99-013XR
99-048-16n	99-094XRA
99-064-15n	99-148XR
99-064-18n	99-144XR
99-092-04n	99-240XRAB
99-092-05n	99-241XRAB
99-095-16n	99-254XRAB
99-105-03n	99-256XRAB
99-126-12n	99-410XRAB
99-130-03n	99-474XRAB

MONSANTO

Food • Health • Hope



If you have any questions concerning these reports, please do not hesitate to contact me at (b) (6), (b) (7)(C)

Sincerely, /

(b) (6), (b) (7)(C)

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

1999 Wheat Field Test Report
USDA # 99-048-16n Monsanto # 99-094XRA

(b) (6), (b) (7)(C)
November 16, 2000

Monsanto Company

Location	County	State
(b) (6), (b) (7)(C), (b) (4)	Bingham	ID
	Teton	MT
	Pondera	MT
	Cass	ND (NOT PLANTED)
	Mountrail	ND
	Burke	ND
(b) (4)	Sherman	OR
(b) (6), (b) (7)(C), (b) (4)	Whitman	WA
(b) (4)	Walla Walla	WA

Bingham County, ID

Planting Date: April 19, 1999

Destruct/Harvest Date July 22, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)
(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)
(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)
(b) (4)

Monitoring for Volunteer Plants: (b) (4)

Teton County, MT

Planting Date: May 19, 1999

Harvest Date: August 23, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Method of devitalization: (b) (4)

Pondera County, MT

Planting Date: May 4, 1999

Destruct/ Harvest Date: August 25, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:

(b) (4)

(b) (4)

Disposition of the seed:

(b) (4)

Mountrail County, ND

Planting Date: May 13, 1999

Harvest Date: August 5, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants

(b) (4)

(b) (4)

Burke County, ND

Planting Date: May 19, 1999

Harvest Date: September 17, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

OR120018_BR_012436

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

(b) (4)

Sherman County, OR.

Planting Date: March 26, 1999

Destruct Date (if not harvested): July 8, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

Whitman County, WA

Planting Date: March 25, 1999

Harvest Date: August 5, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

OR120018_BR_012437

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

Disposition of the seed:

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

(b) (4)

Walla Walla County, WA

Planting Date: April 14, 1999

Harvest Date: August 16, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility

(b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics

(b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

(b) (4)

2/25/99 4:54 pm

Notification Tracking Sheet

Bp number: 99-056-10n

App number: 99-096XR
Received: 2/25/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/27/99
Phenotype: HT - Glyphosate tolerant

Begin movement:
End movement:
Begin release: 3/25/99
End release: 3/24/00
Acre: 50.00
CBI status: CBI

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway North

Address3:

Address4:

City/State/Zip: St. Louis, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax: 314-737-7085

- | | Initial | Date |
|--|----------------|--------------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>all</i>] | [2/25/99] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>JW</i>]* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [<i>BGS</i>] | [3/1/99]* <i>fed x</i> |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Release	*	*MN	*	1*NER	*	[]
Release	*	*MT	*	2*WR	*	[]
Release	*	*ND	*	3*SCR	*	[]
Release	*	*OR	*	1*WR	*	[]
Release	*	*SD	*	2*SCR	*	[]
Release	*	*WA	*	1*WR	*	[]

- | | | |
|--|----------------|--------------------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>all</i>] | [2/24/99] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>BGS</i>] | [4/8/99]* <i>faxed</i> |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>BGS</i>] | [4/12/99] |

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
99-096XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

23-Feb-99

99-056-10n

1. USDA Reference Number

2. Applicant Reference Number

99-096XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Village Pkwy
St. Louis, MO 63198

4. Duration of Introduction

Release

3/25/99 - 3/24/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

Glyphosate tolerant

CONFIDENTIAL

Monsanto Reference ID
99-096XR

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMoVa/I5 -- [(b) (4)

] - CBI

CBI

* Gene: CTP2-CP4 -- [(b) (4)

] - CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMP3/I5 -- [(b) (4)

* Gene: CTP2-CP4 -- [(b) (4)

] - CBI

CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-096XR

7. Mode of Transformation Particle Bombardment

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)
SD(2)

MT(2)
WA(1)

ND(3)

OR(1)

MN

* [REDACTED] (b) (6), (b) (7)(C), (b) (4) [REDACTED], Wilkin County,
MN. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (6), (b) (7)(C), (b) (4) [REDACTED] Wilkin County, MN up to 5
acres.

Comments: Township: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

MT

* [REDACTED] (b) (4) [REDACTED], Gallatin County, MT. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Judith Basin County, MT Up to 5 acres.

* [REDACTED] (b) (4) [REDACTED], Gallatin County, MT. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (6), (b) (7)(C), (b) (4) [REDACTED], Sheridan County, MT up to 5 acres.

ND

* [REDACTED] (b) (6), (b) (7)(C), (b) (4) [REDACTED] Wilkin County,
MN. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (6), (b) (7)(C), (b) (4) [REDACTED], Richland County, ND Up to 5 acres.

* [REDACTED] (b) (4) [REDACTED], ND. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (6), (b) (7)(C), (b) (4) [REDACTED], McHenry County, ND up to 5 acres.

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Monsanto Reference ID
99-096XR

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
23-Feb-99

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

99-096XR

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

23-Feb-99

99-056-10n

1. USDA Reference Number

2. Applicant Reference Number

99-096XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Release

3/25/99 - 3/24/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

Glyphosate tolerant

Monsanto Reference ID
99-096XR

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-096XR

7. Mode of Transformation Particle Bombardment

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)
SD(2)

MT(2)
WA(1)

ND(3)

OR(1)

MN

*, [REDACTED], Wilkin County,
MN. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4), Wilkin County, MN up to 5 acres.

Comments: Township: (b) (6), (b) (7)(C), (b) (4)

MT

* [REDACTED] (b) (4), Gallatin County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: Judith Basin County, MT Up to 5 acres.

* [REDACTED] (b) (4), Gallatin County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4), Sheridan County, MT up to 5 acres.

ND

* [REDACTED] (b) (6), (b) (7)(C), (b) (4) Wilkin County,
MN. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4), Richland County, ND Up to 5 acres.

* [REDACTED] (b) (4), ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4), McHenry County, ND up to 5 acres.

* [REDACTED] (b) (4), Traverse County, SD. Contact:
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4), Dickey County, ND Up to 5 acres.

Monsanto Reference ID
99-096XR

OR

* [REDACTED] (b) (4), Benton County, OR. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: [REDACTED] (b) (4), Umatilla County,
OR Up to 5 acres.

SD

* [REDACTED] (b) (4), Traverse County, SD. Contact:
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4), (b) (6), (b) (7)(C), Brown County, SD Up to 5 acres.

* [REDACTED] (b) (4) Traverse County, SD. Contact:
(b) (6), (b) (7)(C), (b) (4)

Release Location: Marshall County, SD Up to 5 acres.

WA

* [REDACTED] (b) (6), (b) (7)(C), (b) (4), Grant County, WA, (b) (6), (b) (7)(C), (b) (4).

Release Location: Grant County, WA Up to 5 acres.

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Monsanto Reference ID
99-096XR

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

23-Feb-99

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CBI DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID

99-096XR

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

23-Feb-99

99-056-10n

1. USDA Reference Number

2. Applicant Reference Number

99-096XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Release

3/25/99 - 3/24/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

Glyphosate tolerant

Monsanto Reference ID
99-096XR

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-096XR

7. Mode of Transformation Particle Bombardment

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)
SD(2)

MT(2)
WA(1)

ND(3)

OR(1)

MN

* [REDACTED] (b) (4), Wilkin County,
MN. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Wilkin County, MN up to 5 acres.

Comments: Township: (b) (4)

MT

* [REDACTED] (b) (4), Gallatin County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: Judith Basin County, MT Up to 5 acres.

* [REDACTED] (b) (4), Gallatin County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), Sheridan County, MT up to 5 acres.

ND

* [REDACTED] (b) (4), Wilkin County,
MN. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), Richland County, ND Up to 5 acres.

* [REDACTED] (b) (4), ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), McHenry County, ND up to 5 acres.

* [REDACTED] (b) (4), Traverse County, SD. Contact:
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), Dickey County, ND Up to 5 acres.

Monsanto Reference ID
99-096XR

OR

*, (b) (6), (b) (7)(C), (b) (4) [REDACTED], Benton County, OR. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (4) [REDACTED], Umatilla County,
OR Up to 5 acres.

SD

* (b) (6), (b) (7)(C), (b) (4) [REDACTED], Traverse County, SD. Contact:
(b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: (b) (6), (b) (7)(C), (b) (4) [REDACTED], Brown County, SD Up to 5 acres.

*, (b) (6), (b) (7)(C), (b) (4) [REDACTED], Traverse County, SD. Contact:
(b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Marshall County, SD Up to 5 acres.

WA

* (b) (6), (b) (7)(C), (b) (4) [REDACTED], Grant County, WA, (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Location: Grant County, WA Up to 5 acres.

MONSANTO

Food • Health • Hope



CBI DELETED

Monsanto Reference ID
99-096XR

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
23-Feb-99

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 25, 1999

Dear Dr. Hanks:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: J. Burch, PPQ, Pickerington, OH

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012458

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 25, 1999

Dear Dr. Gingery:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012459

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 25, 1999

Dear Mr. Nelson:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012460

file copy

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

February 25, 1999

Dear Mr. Griesbach:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012461

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 25, 1999

Dear Mr. Fridley:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012462

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 25, 1999

Dear Mr. Wessels:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012463



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 25, 1999

Dear Dr. Hanks:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: J. Burch, PPQ, Pickerington, OH

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 4-8-99

State: MN



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OR120018_BR_012464

4-8-99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 25, 1999

Dear Dr. Gingery:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: March 5, 1999

State: Montana



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OR120018_BR_012465

3-5-99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 25, 1999

Dear Mr. Nelson:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID R NELSON

Signature: (b) (6), (b) (7)(C)

Date: 3-2-99

State: ND



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OR120018_BR_012466



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. John Griesbach
Oregon Department of Agriculture
Plant Division
635 Capitol St., N.E.
Salem, OR 97310-0110

February 25, 1999

Dear Mr. Griesbach:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Daniel J. Hilburn

Signature: (b) (6), (b) (7)(C)

Date: March 9, 1999

State: Oregon



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OR120018_BR_012467



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182



February 25, 1999

Dear Mr. Fridley:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/2/99

State: South Dakota





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 25, 1999

Dear Mr. Wessels:

Enclosed is notification 99-056-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-056-10n	Applicant #:	99-096XR
Received:	February 25, 1999	Effective:	March 27, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	MN MT ND OR SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 3/2/99

State: W



April 8, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after April 8, 1999.

Release

Notification no. 99-056-10n (99-096XR)

Regulated article - Wheat

Destinations - Minnesota, Montana, North Dakota, Oregon, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
G. Gingery, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
J. Griesbach, Oregon, Dept. of Agric., Salem, OR
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Brownsville, TX
J. Burch, PPQ, NER, Pickerington, OH
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-056-10n

OR120018_BR_012470

Confirmation Report-Memory Send

Time : 04-09-99 12:49pm
Tel line 1 : +3017348910
Tel line 2 : +
Name : USDA

Job number : 999
Date : 04-09 12:48pm
To : 913147377085
Document Pages : 01
Start time : 04-09 12:48pm
End time : 04-09 12:49pm
Pages sent : 01

Job number : 999

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 8, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear

(b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after April 8, 1999.

Release

Notification no. 99-056-10n (99-096XR)

Regulated article - Wheat

Destinations - Minnesota, Montana, North Dakota, Oregon, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
G. Gingery, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
J. Griesbach, Oregon, Dept. of Agric., Salem, OR
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Brownsville, TX
J. Burch, PPQ, NER, Pickerington, OH
R. Stoaks, PPQ, WR, Sacramento, CA



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OR120018_BR_012471

MONSANTO

Food • Health • Hope



April 9, 1999

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Ms. E. Dianne Hatmaker
Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Road
Riverdale, MD 20737

Reference: USDA 99-048-14N/Monsanto #99-096XAB, Wheat
USDA 99-056-10N/Monsanto #99-096XR, Wheat

Dear Ms. Hatmaker,

This information has been inadvertently omitted from these notifications. I am submitting the additional information that will correct our previous requests. This letter supersedes the one to you dated April 7, 1999 on this same subject.

99-048-14N (b) (6), (b) (7)(C), (b) (4) (b) (4) Wilkin County, MN
(on day of planting, part of the seed will be transported, by car,
to a field release site in Richland County, ND)

(b) (6), (b) (7)(C), (b) (4) (b) (4) McHenry County, ND
(on day of planting, part of the seed will be transported, by car, to
a field release site in Sheridan County, MT)

(b) (6), (b) (7)(C), (b) (4) (b) (4)
Address: (b) (6), (b) (7)(C), (b) (4) SD (b) (6), (b) (7)(C), (b) (4)
Marshall County, SD in place of Traverse County, SD
(on day of planting, part of the seed will be transported, by car, to
field release sites in Brown County, SD and Dickey County, ND).

All of the release sites are covered under 98-056-10N

OR120018_BR_012472

Ms. E. Dianne Hatmaker
USDA
Page 2

99-056-10N The release site in Judith Basin County, MT – the county is correct but the researcher information is incorrect.

Change to: (b) (4), (b) (6), (b) (7)(C) [REDACTED], (b) (4),

(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), (b) (6), (b) (7)(C),
MT (b) (4), (b) (6), (b) (7)(C) Judith Basin County, MT, up to 5 acres.

(b) (4), (b) (6), (b) (7)(C), (b) (4), (b) (6), (b) (7)(C)

Release Location (b) (4), (b) (6), (b) (7)(C), Sheridan County, MT, up to 5 acres.

Thanks for your help!

Sincerely,

(b) (6), (b) (7)(C)

cc: M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
G. Gingery, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD

1999 Wheat Field Trial Report
USDA # 99-056-10n Monsanto # 99-096XR

(b) (6), (b) (7)(C)

December 12, 2000
Monsanto Company

Location

	County	State
(b) (4)	Wilkin	MN
(b) (6), (b) (7)(C), (b) (4)	Judith Basin	MT
(b) (6), (b) (7)(C), (b) (4)	Sheridan	MT
(b) (6), (b) (7)(C), (b) (4)	Dickey	ND
	Richland	ND
	McHenry	ND
(b) (4)	Umatilla	OR
(b) (6), (b) (7)(C), (b) (4)	Brown	SD
(b) (4)	Marshall	SD
(b) (6), (b) (7)(C), (b) (4)	Grant	WA

Wilkin County, MN

Planting Date: May 3, 1999

Destruct/Harvest Date: August 15, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Judith Basin, MT

Planting Date: (b) (4)

Sheridan County, MT

Planting Date: May 8, 1999

Destruct/Harvest Date: September 24, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Dickey County, ND

Planting Date: May 26, 1999

Destruct/Destruct Date: August 27, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Richland County, ND

Planting Date: May 1, 1999

Destruct/Harvest Date: August 10, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

McHenry County, ND

Planting Date: May 13, 1999

Destruct/ Harvest Date: August 23, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Umatilla County, OR

Planting Date: April 24, 1999

Destruct/ Harvest Date: August 17, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)
(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Brown County, SD

Planting Date: May 26, 1999

Destruct/Harvest Date: August 26, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Marshall County, SD

Planting Date: May 20, 1999

Destruct/Harvest Date: September 21, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Grant County, WA

Planting Date: April 13, 1999

Destruct/Harvest Date: August 9, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

3/05/99 5:59 pm

Notification Tracking Sheet

Bp number: 99-064-15n

App number: 99-148XR
Received: 3/05/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 4/04/99
Phenotype: HT - Glyphosate tolerant

Begin movement:
End movement:
Begin release: 4/01/99
End release: 3/31/00
Acre: 15.00
CBI status: CBI

Comments:

Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Fax: 314-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[all]	[3/5/99]
2. <input type="checkbox"/> Review by biotechnologist	[JW]*	[3/8/99]*
3. <input checked="" type="checkbox"/> Letter of notification to State	[BG]	[3/11/99]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg
Release	*	*ND	*	1*SCR *
Release	*	*SD	*	1*SCR *
Release	*	*WA	*	1*WR *

	Initial	Date
5. <input checked="" type="checkbox"/> Enter genes into database	[all]	[3/8/99]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw	[bg]	[3/22/99]*
7. <input checked="" type="checkbox"/> Enter final data into database	[bg]	[3/23/99]

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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-148XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

02-Mar-99

99-064-15n

1. USDA Reference Number

2. Applicant Reference Number 99-148XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy

St. Louis, MO 63198

4. Duration of Introduction

Release

4/1/99 - 3/31/2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype glyphosate tolerant

Cultivar(s)/Variety(ies): Bob White

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Monsanto Reference ID
99-148XR

designation of transformed line: 71600, 71700, 71800

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [(b) (4)]
[REDACTED] - CBI CBI
- * Gene: CTP2-CP4 -- [(b) (4)]
[REDACTED]
[REDACTED]] - CBI
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [(b) (4)]
[REDACTED] - CBI
- * Gene: CTP2-CP4 -- [(b) (4)]
[REDACTED]
[REDACTED]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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Monsanto Reference ID
99-148XR

designation of transformed line: 71500

Constructs: PV-TXGT11

genotype:

Gene of Interest

* Promoter: CMP 3/I5 -- [REDACTED] (b) (4)] - CBI CBI
* Gene: CTP2-CP4 -- [REDACTED] (b) (4)
[REDACTED]
[REDACTED]] - CBI
* Terminator: NOS 3' +2 -- [REDACTED] (b) (4)
[REDACTED]] - CBI

Gene of Interest

* Promoter: CMoVa/I5 + leader1 -- [REDACTED] (b) (4) CBI
[REDACTED]
[REDACTED] - CBI
* Gene: CTP2-CP4 -- [REDACTED] (b) (4) CBI
[REDACTED]
[REDACTED] - CBI
* Terminator: M1 3' -- [REDACTED] (b) (4)
[REDACTED]
] - CBI CBI

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Monsanto Reference ID
99-148XR

designation of transformed line: 71400

Constructs: PV-TXGT12

genotype:

Gene of Interest

* Promoter: MP4 -- [(b) (4)

[REDACTED]

CBI

* Gene: CTP2-CP4 -- [(b) (4)

[REDACTED]

] - CBI

* Terminator: M1 -- [(b) (4)

[REDACTED]

- CBI

CBI

Gene of Interest

* Promoter: CMP 3/I5 -- [(b) (4)

[REDACTED]

- CBI

CBI

* Gene: CTP7-CP4 -- [(b) (4)

[REDACTED]

- CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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Monsanto Reference ID
99-148XR

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(1) SD(1) WA(1)

ND

* [REDACTED] (b) (4), McHenry County, ND. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) McHenry County, ND up to 5 acres.

SD

* [REDACTED] (b) (4), Traverse County, SD. Contact:
(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), Traverse County, SD up to 5 acres.

WA

* [REDACTED] (b) (4), Grant County, WA. Contact: (b) (4), (b) (6), (b) (7)(C),
(b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4), Grant County, WA up to 5 acres.

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Monsanto Reference ID
99-148XR

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
02-Mar-99

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into potatoes and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant potatoes for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable

OR120018_BR_012487

knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for tomatoes has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

Some of the potato cultivars are claimed as confidential because disclosure of the variety name would identify a confidential business partner which has not been publicly announced.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[]", as labeled as CBI.

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CBI DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

99-148XR

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

02-Mar-99

99-064-15n

1. USDA Reference Number

2. Applicant Reference Number

99-148XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Release

4/1/99 - 3/31/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate tolerant

Cultivar(s)/Variety(ies): Bob White

Monsanto Reference ID
99-148XR

designation of transformed line: 71600, 71700, 71800

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-148XR

designation of transformed line: 71500

Constructs: PV-TXGT11

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3'+2 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMoVa/I5 + leader1 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID
99-148XR

designation of transformed line: 71400

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-148XR

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(1)

SD(1)

WA(1)

ND

*

(b) (4)

McHenry County, ND. Contact (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) McHenry County, ND up to 5 acres.

SD

*

(b) (4)

Traverse County, SD. Contact:

(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Traverse County, SD up to 5 acres.

WA

*

(b) (4)

Grant County, WA. (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Grant County, WA up to 5 acres.

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Monsanto Reference ID
99-148XR

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

02-Mar-99

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OR120018

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Monsanto Reference ID
99-148XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

02-Mar-99

99-064-15n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

99-148XR

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company

EMail

(b) (6), (b) (7)(C) @monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. Duration of Introduction

Release

4/1/99 - 3/31/2000

5. Recipient
- Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate tolerant

Cultivar(s)/Variety(ies): Bob White

Monsanto Reference ID
99-148XR

designation of transformed line: 71600, 71700, 71800

Constructs: PV-TXGT10

genotype:

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMoVa/I2 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-148XR

designation of transformed line: 71500

Constructs: PV-TXGT11

genotype:

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' +2 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMoVa/I5 + leader1 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 3' -- [CBI Deleted]

Monsanto Reference ID
99-148XR

designation of transformed line: 71400

Constructs: PV-TXGT12

genotype:

Gene of Interest

- * Promoter: MP4 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: M1 -- [CBI Deleted]

Gene of Interest

- * Promoter: CMP 3/I5 -- [CBI Deleted]
- * Gene: CTP7-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-148XR

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(1)

SD(1)

WA(1)

ND

*

(b) (4)

McHenry County, ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) McHenry County, ND up to 5 acres.

SD

*

(b) (4)

Traverse County, SD. Contact:

(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Traverse County, SD up to 5 acres.

WA

*

(b) (4)

Grant County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Grant County, WA up to 5 acres.

MONSANTO

Food • Health • Hope



DELETED

Monsanto Reference ID
99-148XR

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

02-Mar-99

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 5, 1999

Dear Mr. Nelson:

Enclosed is notification 99-064-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-15n	Applicant #:	99-148XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012501

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

March 5, 1999

Dear Mr. Fridley:

Enclosed is notification 99-064-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-15n	Applicant #:	99-148XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012502

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

March 5, 1999

Dear Mr. Wessels:

Enclosed is notification 99-064-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-15n	Applicant #:	99-148XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012503



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 5, 1999

Dear Mr. Nelson:

Enclosed is notification 99-064-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-15n	Applicant #:	99-148XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID NELSON

Signature:

(b) (6), (b) (7)(C)

Date: 3-12-99

State: ND



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An Equal Opportunity Employer

OR120018_BR_012504

3/12/99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

March 5, 1999

Dear Mr. Fridley:

Enclosed is notification 99-064-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-15n	Applicant #:	99-148XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 3/15/99

State: South Dakota



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An Equal Opportunity Employer

OR120018_BR_012505



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

March 5, 1999

Dear Mr. Wessels:

Enclosed is notification 99-064-15n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-15n	Applicant #:	99-148XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Thomas L. Wessels*

Signature: (b) (6), (b) (7)(C)

Date: *3/13/99*

State: *WA*



3/12/99

March 22, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after April 4, 1999.

Release

Notification no. 99-064-15n (99-148XR)

Regulated article - Wheat

Destinations - North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Brownsville, TX
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-064-15n

OR120018_BR_012507

1999 Wheat Field Trial Report
USDA # 99-064-15n Monsanto # 99-148XR

(b) (6), (b) (7)(C)
November 30, 2000
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
Prairie Agricultural Research	Marshall	SD
Qualls Agricultural Labs	Grant	WA
Agro-Tech, Inc.	McHenry	ND (Not Planted)

Marshall County, SD

Planting Date: May 19, 1999

Destruct/Harvest Date: August 19, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Method of Devitalization or Final Disposition of Plot area after Harvesting: (b) (4)

Grant County, WA

Planting Date: April 15, 1999

Destruct/Harvest Date: August 10, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Method of Devitalization or Final Disposition of Plot area after Harvesting: (b) (4)

CONFIDENTIAL

1999 Wheat Field Test Report
USDA #99-064-15n Monsanto #99-148XR

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
7408	McHenry	ND	Not Planted
1133	Marshall	SD	
519	Grant	WA	

Marshall County/SD (1133)

Planting Date: 05/19/1999

Harvest Date: 08/19/1999

Vector Constructs/Line Numbers Planted: (b) (4)
[REDACTED] CBI

Purpose of Field Trial: [(b) (4)] - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

[REDACTED]
- CBI

Field Monitoring Observations for Insect Susceptibility: (b) (4)

[REDACTED]
- CBI

Disposition of the Harvested Material: [(b) (4)] - CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)
[REDACTED] - CBI

Monitoring for Volunteer Plants: (b) (4)
[REDACTED] - CBI

Grant County/WA (519)

Planting Date: 04/15/1999

Harvest Date: 08/10/1999

Vector Constructs/Line Numbers Planted: (b) (4)

- CBI

Purpose of Field Trial: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

- CBI

Field Monitoring Observations for Insect Susceptibility: (b) (4)

- CBI

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

- CBI

Field Monitoring Observations for Weediness Characteristics: (b) (4)

- CBI

Field Monitoring Observations for Plant Stand: (b) (4)

- CBI

Disposition of the Harvested Material: (b) (4) - CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

- CBI

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

1999 Wheat Field Test Report
USDA #99-064-15n Monsanto #99-148XR

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
7408	McHenry	ND	Not Planted
1133	Marshall	SD	
519	Grant	WA	

Marshall County/SD (1133)

Planting Date: 05/19/1999

Harvest Date: 08/19/1999

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Grant County/WA (519)

Planting Date: 04/15/1999

Harvest Date: 08/10/1999

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

MONSANTO

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December 7, 2000

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notifications it was discovered an incorrect county was listed.

USDA #	Monsanto #
99-064-18n	99-144XR
99-064-15n ✓	99-148XR

In both notifications the site Traverse county was incorrectly listed, it should have read Marshall County, SD. Traverse County is in Minnesota.

I apologize for any inconvenience this may cause. Please call me at (b) (6), (b) (7)(C), if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc: Kevin Fridley, South Dakota Department of Agriculture
Dana DeWeese, Regional Biotechnologist

OR120018_BR_012514

MONSANTO

Food • Health • Hope



December 8, 2000

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

<u>USDA Number</u>	<u>Monsanto number</u>
98-333-06n	98-040XR
98-035-04n	98-042XR
98-224-03n	98-313XR
98-229-11n	98-324XRAB
98-261-03n	98-382XRAB
98-261-04n	98-383XRAB
99-039-13n	99-053XRAB
99-039-14n	99-054XRAB
99-047-09n	99-011XR
99-047-11n	99-013XR
99-048-16n	99-094XRA
99-064-15n	99-148XR
99-064-18n	99-144XR
99-092-04n	99-240XRAB
99-092-05n	99-241XRAB
99-095-16n	99-254XRAB
99-105-03n	99-256XRAB
99-126-12n	99-410XRAB
99-130-03n	99-474XRAB

OR120018_BR_012515

MONSANTO

Food • Health • Hope



If you have any questions concerning these reports, please do not hesitate to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

3/05/99 5:59 pm

Notification Tracking Sheet

Bp number: 99-064-18n

App number: 99-144XR
Received: 3/05/99
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 4/04/99
Phenotype: HT - Glyphosate tolerant

Begin movement:
End movement:
Begin release: 3/31/99
End release: 3/30/00
Acre: 15.00
CBI status: CBI

Comments:

Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C) (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Fax: 314-737-7085

- | | Initial | Date |
|--|----------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>hly</i>] | [3/5/99] |
| 2. <input type="checkbox"/> Review by biotechnologist | [<i>QN</i>]* | []* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State | [<i>BG</i>] | [3/11/99]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Release	*	*ND	*	1*SCR *
Release	*	*SD	*	1*SCR *
Release	*	*WA	*	1*WR *

- | | | |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>hly</i>] | [3/8/99] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>hly</i>] | [3/22/99]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>hly</i>] | [3/23/99] |

MONSANTO

Food · Health · Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

http://www.monsanto.com

Monsanto Reference ID

99-144XR

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 20737

01-Mar-99

99-064-18n

1. USDA Reference Number

2. Applicant Reference Number

99-144XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

Monsanto Company

E-Mail

(b) (6), (b) (7)(C) @monsanto.com

700 Chesterfield Village Pkwy

St. Louis, MO 63198

4. Duration of Introduction

Release

3/31/99 - 3/30/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate-tolerant

Cultivar(s)/Variety(ies): Bob White

CONFIDENTIAL

Monsanto Reference ID
99-144XR

designation of transformed line: 71100, 71200, 71300

Constructs: PV-TXGT05

genotype:

Gene of Interest

* Promoter: CMoVa/I5 -- (b) (4)

] - CBI

CBI

* Gene: CTP2-CP4 -- (b) (4)

- CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

* Promoter: CMP3/I5 -- (b) (4)

- CBI

CBI

* Gene: CTP2-CP4 -- (b) (4)

] - CBI

* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
99-144XR

7. Mode of Transformation Particle Bombardment

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(1) SD(1) WA(1)

ND

* [REDACTED] (b) (4) McHenry County, ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: [REDACTED] (b) (4) McHenry County, ND up to 5 acres.

SD

* [REDACTED] (b) (4) Traverse County, SD. Contact:
(b) (6), (b) (7)(C), (b) (4) 6

Release Location: [REDACTED] (b) (4), Traverse County, SD up to 5 acres.

WA

* [REDACTED] (b) (6), (b) (7)(C), (b) (4) Grant County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4), Grant County, WA up to 5 acres.

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Food • Health • Hope

CONFIDENTIAL

Monsanto Reference ID
99-144XR

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company
01-Mar-99

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant corns for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create

essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, And Expressed Traits

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity And Characteristics Of Donor Organism

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for corn have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identity of Recipient Cultivars

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism for corn has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to

Monsanto ID: 99-144XR

identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification of Items claimed as Confidential Business Information

Items claimed as CBI as so indicated in the text as follows: [CBI - Deleted]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, “[]”, as labeled as CBI.

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CBI DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-144XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

01-Mar-99

99-064-18n

1. USDA Reference Number

2. Applicant Reference Number 99-144XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

EMail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Release

3/31/99 - 3/30/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype glyphosate-tolerant

Cultivar(s)/Variety(ies): Bob White

Monsanto Reference ID
99-144XR

designation of transformed line: 71100,71200, 71300

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-144XR

7. Mode of Transformation Particle Bombardment

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(1)

SD(1)

WA(1)

ND

*

(b) (4)

McHenry County, ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) McHenry County, ND up to 5 acres.

SD

*

(b) (4)

Traverse County, SD. Contact:

(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Traverse County, SD up to 5 acres.

WA

*

(b) (6), (b) (7)(C), (b) (4)

, Grant County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4), Grant County, WA up to 5 acres.

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CBI DELETED

Monsanto Reference ID
99-144XR

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

01-Mar-99

MONSANTO

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CBI DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
99-144XR

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 20737

01-Mar-99

99-064-18n

1. USDA Reference Number

2. Applicant Reference Number 99-144XR

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

EMail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Release

3/31/99 - 3/30/2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype

glyphosate-tolerant

Cultivar(s)/Variety(ies): Bob White

Monsanto Reference ID
99-144XR

designation of transformed line: 71100,71200, 71300

Constructs: PV-TXGT05

genotype:

Gene of Interest

- * Promoter: CMoVa/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Gene of Interest

- * Promoter: CMP3/I5 -- [CBI Deleted]
- * Gene: CTP2-CP4 -- [CBI Deleted]
- * Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID
99-144XR

7. Mode of Transformation Particle Bombardment

8. Introduction Release

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(1)

SD(1)

WA(1)

ND

*

(b) (4)

McHenry County, ND. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: REDACTED McHenry County, ND up to 5 acres.

SD

*

(b) (4)

Traverse County, SD. Contact:

(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4), Traverse County, SD up to 5 acres.

WA

*

(b) (6), (b) (7)(C), (b) (4)

, Grant County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4), Grant County, WA up to 5 acres.

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Monsanto Reference ID
99-144XR

CBI 031777

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

01-Mar-99

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 5, 1999

Dear Mr. Nelson:

Enclosed is notification 99-064-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-18n	Applicant #:	99-144XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012534

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

March 5, 1999

Dear Mr. Fridley:

Enclosed is notification 99-064-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-18n	Applicant #:	99-144XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012535

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

March 5, 1999

Dear Mr. Wessels:

Enclosed is notification 99-064-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-18n	Applicant #:	99-144XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

OR120018_BR_012536



Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 5, 1999

Dear Mr. Nelson:

Enclosed is notification 99-064-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-18n	Applicant #:	99-144XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: DAVID R NELSON

Signature:

(b) (6), (b) (7)(C)

Date: 3-12-99

State: ND



3/12/99



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Beltsville, MD 20717

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

March 5, 1999

Dear Mr. Fridley:

Enclosed is notification 99-064-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-18n	Applicant #:	99-144XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

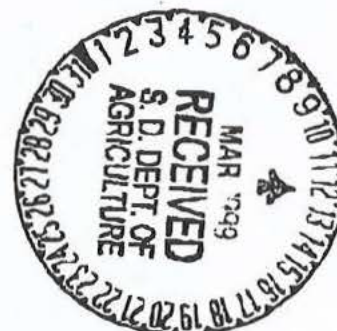
Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 3/15/99

State: South Dakota



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An Equal Opportunity Employer

OR120018_BR_012538



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Pawcatuck, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

March 5, 1999

Dear Mr. Wessels:

Enclosed is notification 99-064-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-064-18n	Applicant #:	99-144XR
Received:	March 5, 1999	Effective:	April 4, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:			
Release destination:	ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 3/12/99

State: WA



APHIS - Planting American Agriculture

AN EQUAL OPPORTUNITY AGENCY

OR120018_BR_012539

3/12/99

March 22, 1999

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Village Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after April 4, 1999.

Release

Notification no. 99-064-18n (99-144XR)

Regulated article - Wheat

Destinations - North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
T. Wessels, Washington Dept. of Agric., Olympia, WA
D. DeWeese, PPQ, SCR, Brownsville, TX
R. Stoaks, PPQ, WR, Sacramento, CA
File number 99-064-18n

OR120018_BR_012540

MONSANTO

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December 8, 2000

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

USDA Number

Monsanto number

98-333-06n	98-040XR
98-035-04n	98-042XR
98-224-03n	98-313XR
98-229-11n	98-324XRAB
98-261-03n	98-382XRAB
98-261-04n	98-383XRAB
99-039-13n	99-053XRAB
99-039-14n	99-054XRAB
99-047-09n	99-011XR
99-047-11n	99-013XR
99-048-16n	99-094XRA
99-064-15n	99-148XR
99-064-18n	99-144XR
99-092-04n	99-240XRAB
99-092-05n	99-241XRAB
99-095-16n	99-254XRAB
99-105-03n	99-256XRAB
99-126-12n	99-410XRAB
99-130-03n	99-474XRAB

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If you have any questions concerning these reports, please do not hesitate to contact me at (b) (6), (b) (7)(C).

Sincerely, /

(b) (6), (b) (7)(C)

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1999 Wheat Field Trial Report
USDA # 99-064-18n Monsanto # 99-144XR

(b) (6), (b) (7)(C)
November 29, 2000
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
Agro- Tech. Inc.	McHenry	ND (Not Planted)
Prairie Agricultural Research	Traverse	SD
Qualls Agricultural Labs	Grant	WA

Marshall County, SD

Planting Date: May 19, 1999

Destruct/Harvest Date: August 19, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Method of Devitalization or Final Disposition of Plot area after Harvesting: (b) (4)

Grant County, WA

Planting Date: April 15, 1999

Destruct/ Harvest Date August 10, 1999

Vector Constructs/Line Numbers Planted (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

OR120018_BR_012543

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

CONFIDENTIAL

**1999 Wheat Field Test Report
USDA #99-064-18n Monsanto #99-144XR**

**AMENDED
December 17, 2002**

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
7408	McHenry	ND	Not Planted
1133	Marshall	SD	
519	Grant	WA	

Marshall County/SD (1133)

Planting Date: 05/19/1999

Harvest Date: 08/19/1999

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)
CBI

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)
- CBI

Disposition of the Harvested Material: (b) (4) - CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4) CBI

Monitoring for Volunteer Plants: (b) (4)

(b) (4) - CBI

Grant County/WA (519)

Planting Date: 04/15/1999

Harvest Date: 08/10/1999

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

CBI

Field Monitoring Observations for Insect Susceptibility: (b) (4)

CBI

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

- CBI

Field Monitoring Observations for Weediness Characteristics: (b) (4)

CBI

Field Monitoring Observations for Plant Stand: (b) (4)

- CBI

Disposition of the Harvested Material: (b) (4) - CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting (b) (4)

- CBI

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

1999 Wheat Field Test Report
USDA #99-064-18n Monsanto #99-144XR

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
7408	McHenry	ND	Not Planted
1133	Marshall	SD	
519	Grant	WA	

Marshall County/SD (1133)

Planting Date: 05/19/1999

Harvest Date: 08/19/1999

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Grant County/WA (519)

Planting Date: 04/15/1999

Harvest Date: 08/10/1999

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

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December 7, 2000

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
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<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notifications it was discovered an incorrect county was listed.

USDA #	Monsanto #
99-064-18n ✓	99-144XR
99-064-15n	99-148XR

In both notifications the site Traverse county was incorrectly listed, it should have read Marshall County, SD. Traverse County is in Minnesota.

I apologize for any inconvenience this may cause. Please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc: Kevin Fridley, South Dakota Department of Agriculture
Dana DeWeese, Regional Biotechnologist

OR120018_BR_012551